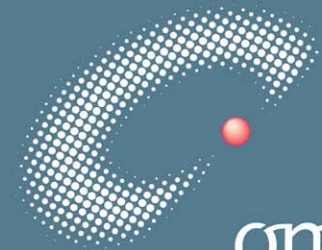


Biorepositories and research

Brian J Clark

NCIN Launch – Transforming Data into
Action.

18th June 2008



onCore^{UK}

Outline of the presentation

- Function of onCore UK – research questions being addressed – partners involved
- Information currently being collected
- Current size, scope and achievements of the project
- Requirements for patient based clinical and related information – what would be the added value of NCIN?
- Future work

Outline of the presentation

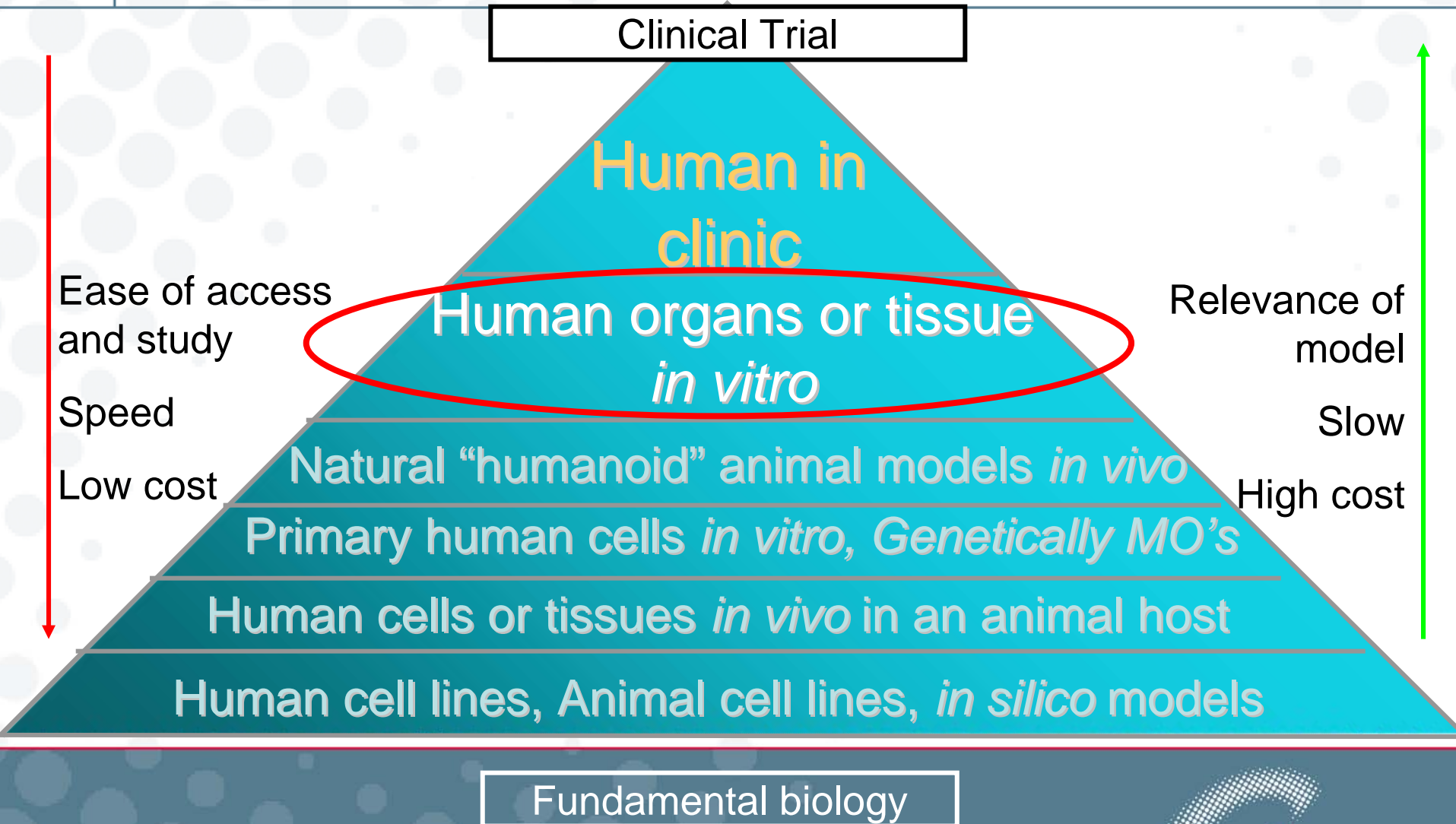
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Our common vision in biomedical research



Source: Cancer World, March/April 2008

Models for human disease



How do we make better use of *Human Biosamples*?

- More samples
- More consistency of sample quality
- A greater range of sample types – *fit for purpose*
- **More complete and consistent accompanying data collection / annotation**
- **More accessible for study – sample and data sharing**
- Better developed legal and ethical frameworks
- Responsible biobanking



“to serve as a national cancer
biosample and information
resource for the development of
new interventions against cancer”

Prevention

Diagnosis

Treatment

Model for new organisation

- An independent charitable company named onCore UK founded in 2005
- A service organisation, not a research unit – no vested interest in the samples
- Only role is to serve patients/donors and researchers
 - Honest custodian and agent between donors and researchers
- Facilitator of the donated sample journey from donor, via healthcare, to researcher

THE NEW ENGLAND JOURNAL of MEDICINE

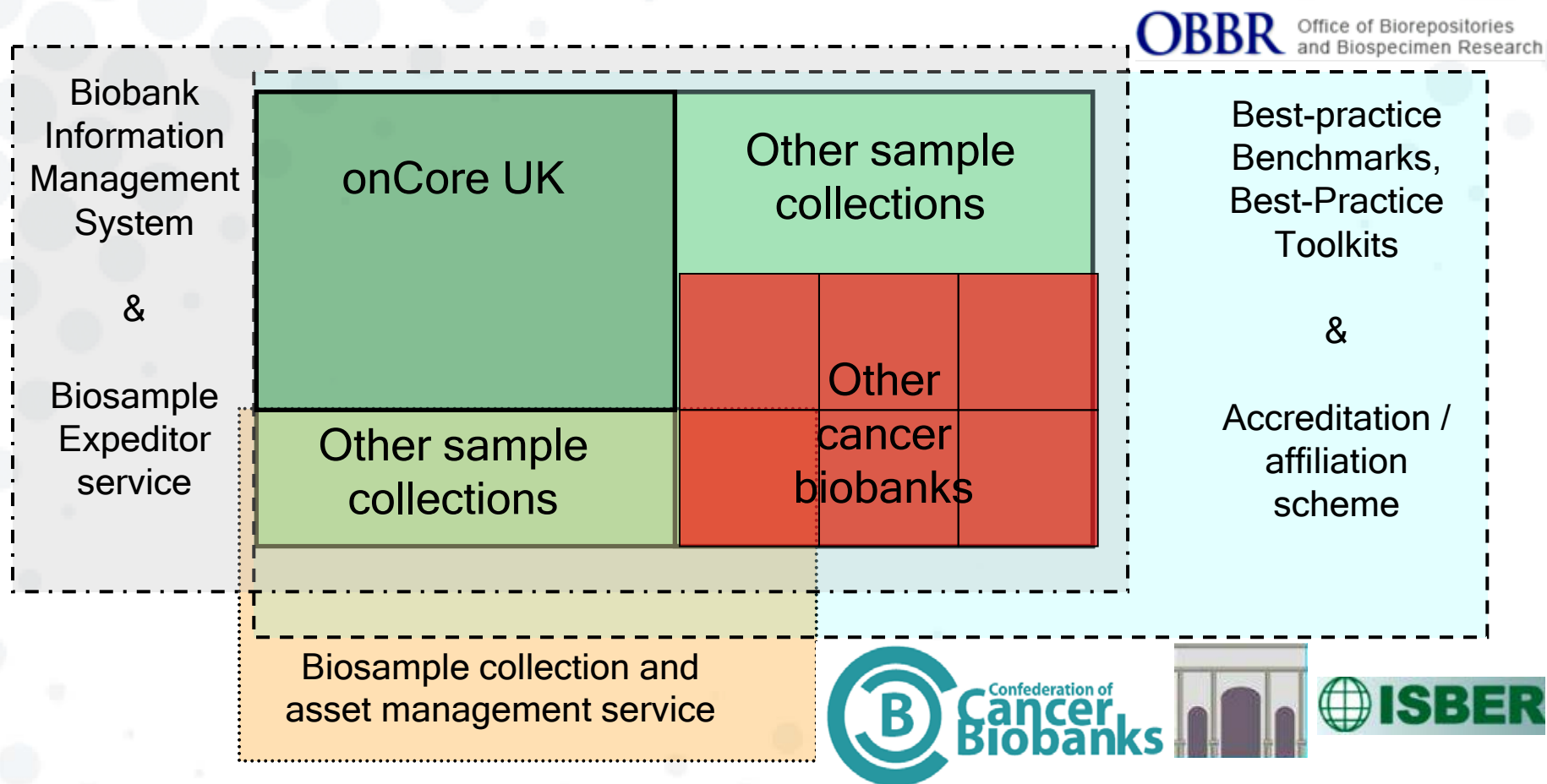
SOUNDING BOARD

The Charitable Trust as a Model for Genomic Biobanks

David E. Winickoff, J.D., and Richard N. Winickoff, M.D.

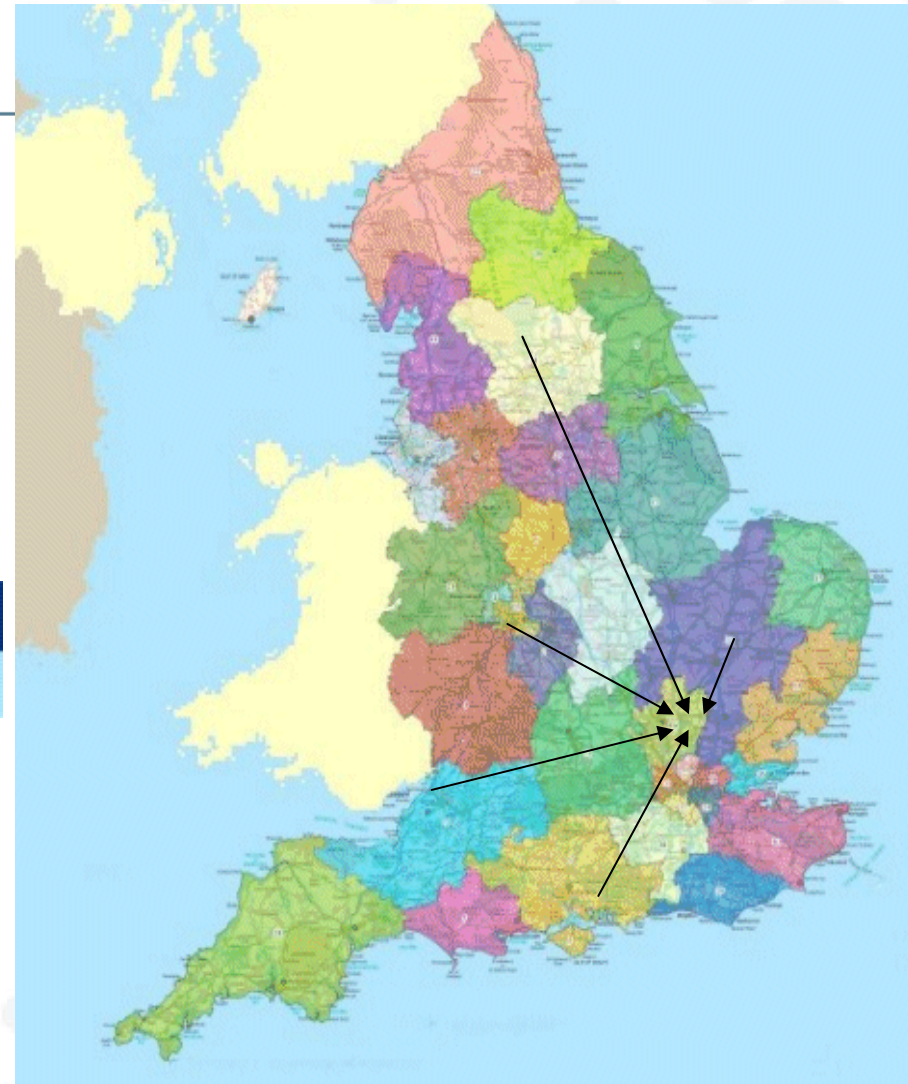


Integrated work-streams to deliver strategy



Sources and storage of samples

- Donor recruitment
- Data and sample collection
- Sample stabilisation
- Sample transport to central repository
- Web application
- Data housed at a central secure data centre



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What is biobanking information?

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

Donor personal data e.g. identifiers, demographics, etc

Donor routine health data e.g. investigations, diagnosis, treatment, follow-up, etc

Donor study-related health data e.g. trial i.d., trial management, study arm, diagnosis, treatment, follow-up, investigations, biomarkers, end-points, etc

Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – onCore UK

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

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Biobank management data e.g. activity based costs, business objects reports, etc

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Sources of biobanking information – NHS partners

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

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Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – Clinical trials

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

Donor personal data e.g. identifiers, demographics, etc

Donor routine health data e.g. investigations, diagnosis, treatment, follow-up, etc

Donor study-related health data e.g. trial i.d., trial management, study arm, diagnosis, treatment, follow-up, investigations, biomarkers, end-points, etc

Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – Sample users

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

Donor personal data e.g. identifiers, demographics, etc

Donor routine health data e.g. investigations, diagnosis, treatment, follow-up, etc

Donor study-related health data e.g. trial i.d., trial management, study arm, diagnosis, treatment, follow-up, investigations, biomarkers, end-points, etc

Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – shared onCore UK / NHS partners

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

Donor personal data e.g. identifiers, demographics, etc

Donor routine health data e.g. investigations, diagnosis, treatment, follow-up, etc

Donor study-related health data e.g. trial i.d., trial management, study arm, diagnosis, treatment, follow-up, investigations, biomarkers, end-points, etc

Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – shared onCore UK / service partners

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

Donor personal data e.g. identifiers, demographics, etc

Donor routine health data e.g. investigations, diagnosis, treatment, follow-up, etc

Donor study-related health data e.g. trial i.d., trial management, study arm, diagnosis, treatment, follow-up, investigations, biomarkers, end-points, etc

Research study sample-related data e.g. study i.d., study PI, analytical methods, results, etc

Biobank management data e.g. activity based costs, business objects reports, etc

System security and stability data e.g. number of enquiries, IP addresses, attempted intrusions, etc

Sources of biobanking information – shared onCore UK / all partners

Sample data e.g. sample type – serum, tumour, QC results, etc

Process data e.g. sample source, SOP, date, time, operator, container batch, etc

Inventory data e.g. addressable storage location, quantity, status, etc

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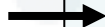
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Quality system

NCIN



Data model

- **Patient Data – based on Department of Health National Cancer Data Set**

- Identifiers
- Demographics
- Diagnosis - Pathology – RCPATH Minimum Data Sets for each cancer type published
- Treatment
 - Trial or not, which trial, number, etc.
 - Outcome
 - No longitudinal data at this time

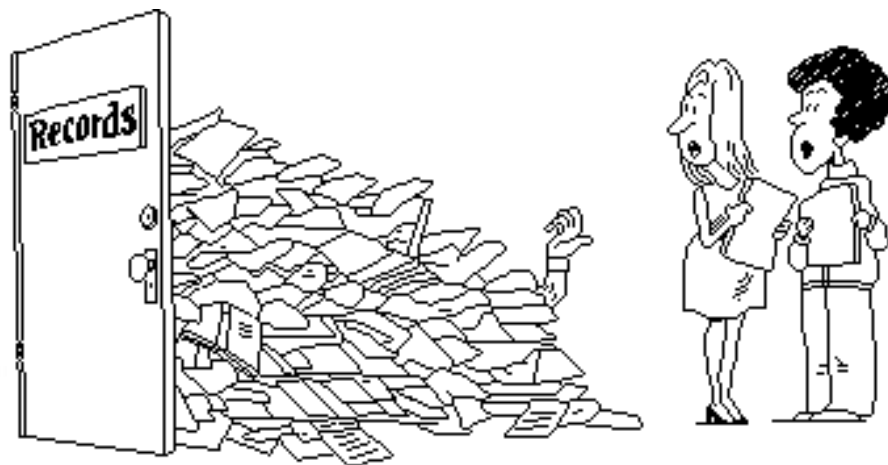


The Royal College of Pathologists

Pathology: the science behind the cure

- **Sample Associated Data**

- Process timestamp
- Protocol ID
- Package and Dispatch



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Partner NHS Trusts

● Central South Coast Cancer Research Network

Southampton 
University Hospitals NHS Trust

Portsmouth Hospitals 
NHS Trust

● West Anglia Cancer Research Network

Cambridge University Hospitals 
NHS Foundation Trust

● Pan Birmingham Cancer Research Network

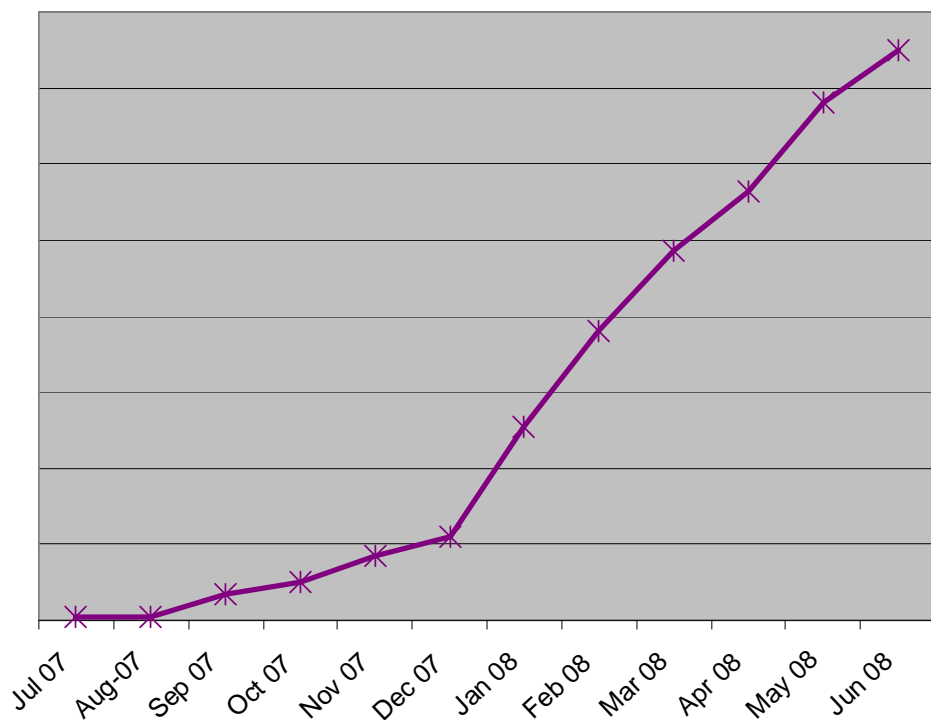
University Hospital 
Birmingham
NHS Foundation Trust

Heart of England 
NHS Foundation Trust

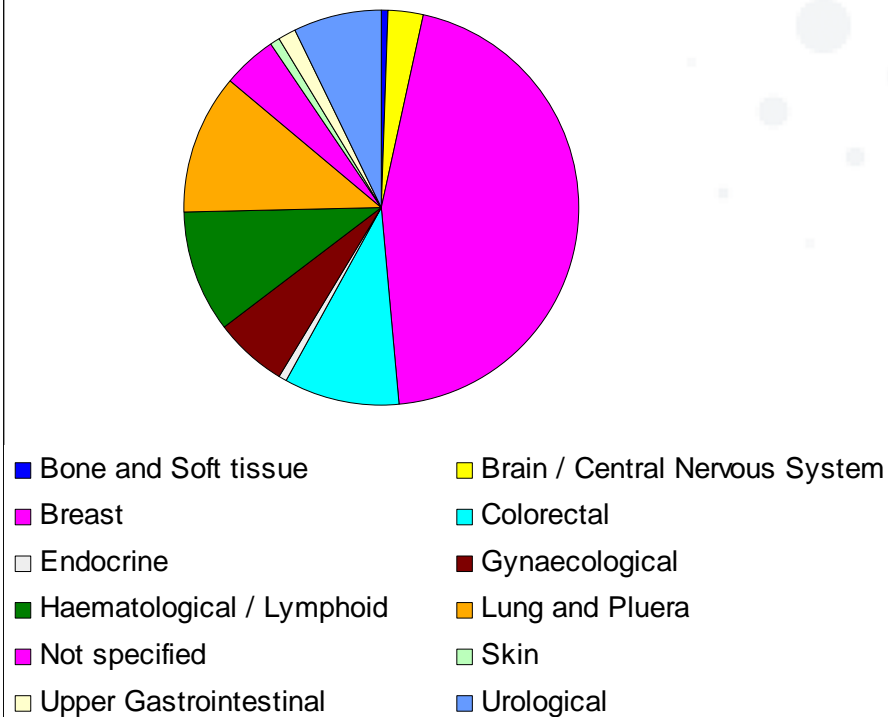
Sandwell and West Birmingham Hospitals 
NHS Trust

Donor and Sample Accrual

Donor Accrual



Body System for Primary Tumour



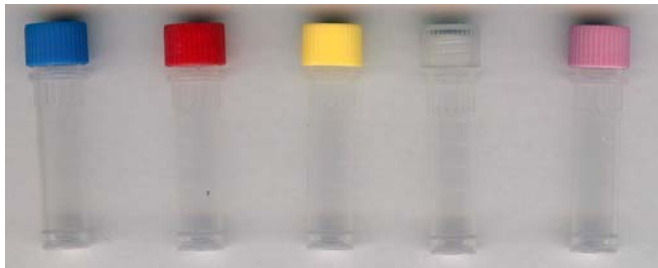
Routine Sample Types

- Peripheral blood
- Formalin fixed, paraffin embedded samples of tumour and where available unaffected tissue from the same organ /site
- No plans to extend beyond these on a routine basis at present, but can do in special circumstances

Blood samples

- Aim to collect 50 ml of blood in ways to accommodate undefined future uses – serum, plasma, buffy coat, red cells, cryopreserved cells, dried blood spots
- All tubes barcoded – no writing required by operators
- Relationship between donors, blood tubes and aliquots built via web interface to biobank information management system as processing proceeds

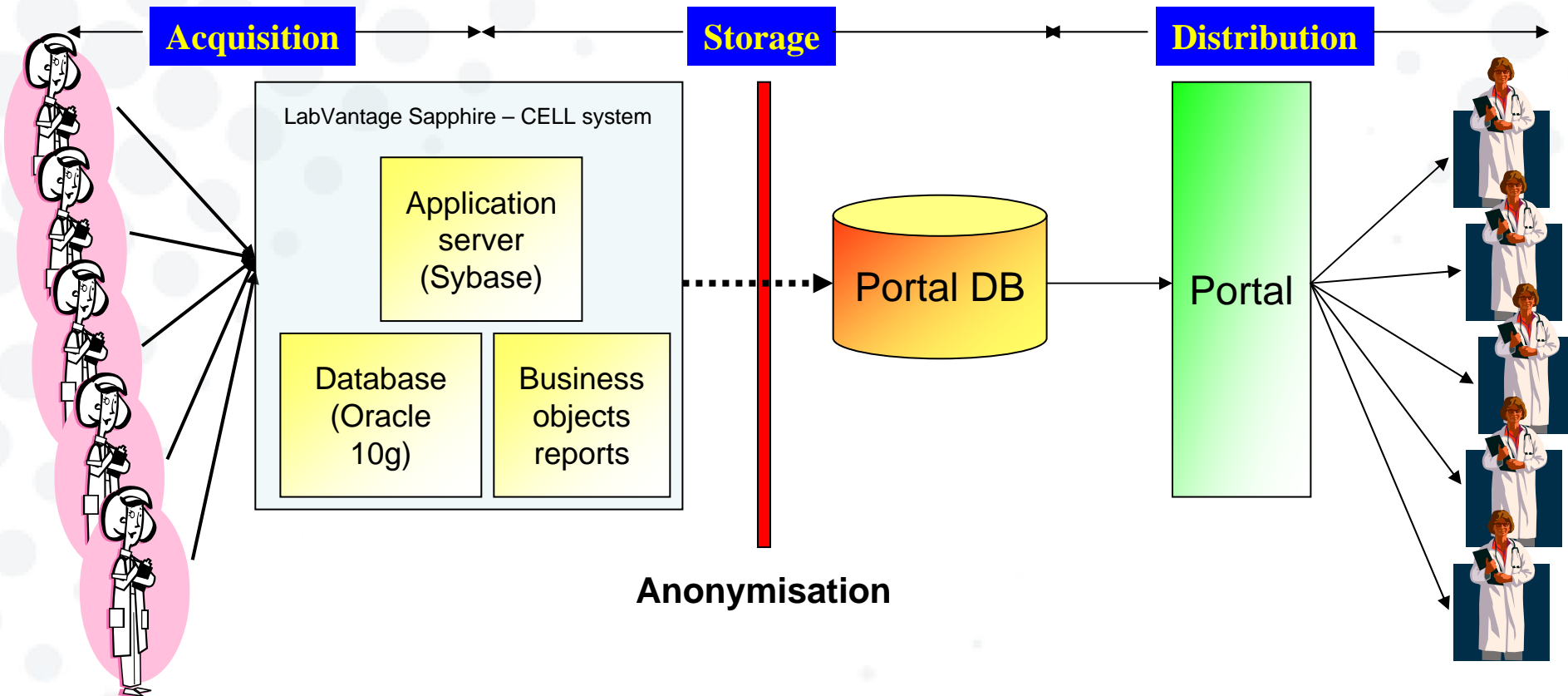
Sample tubes, barcoding



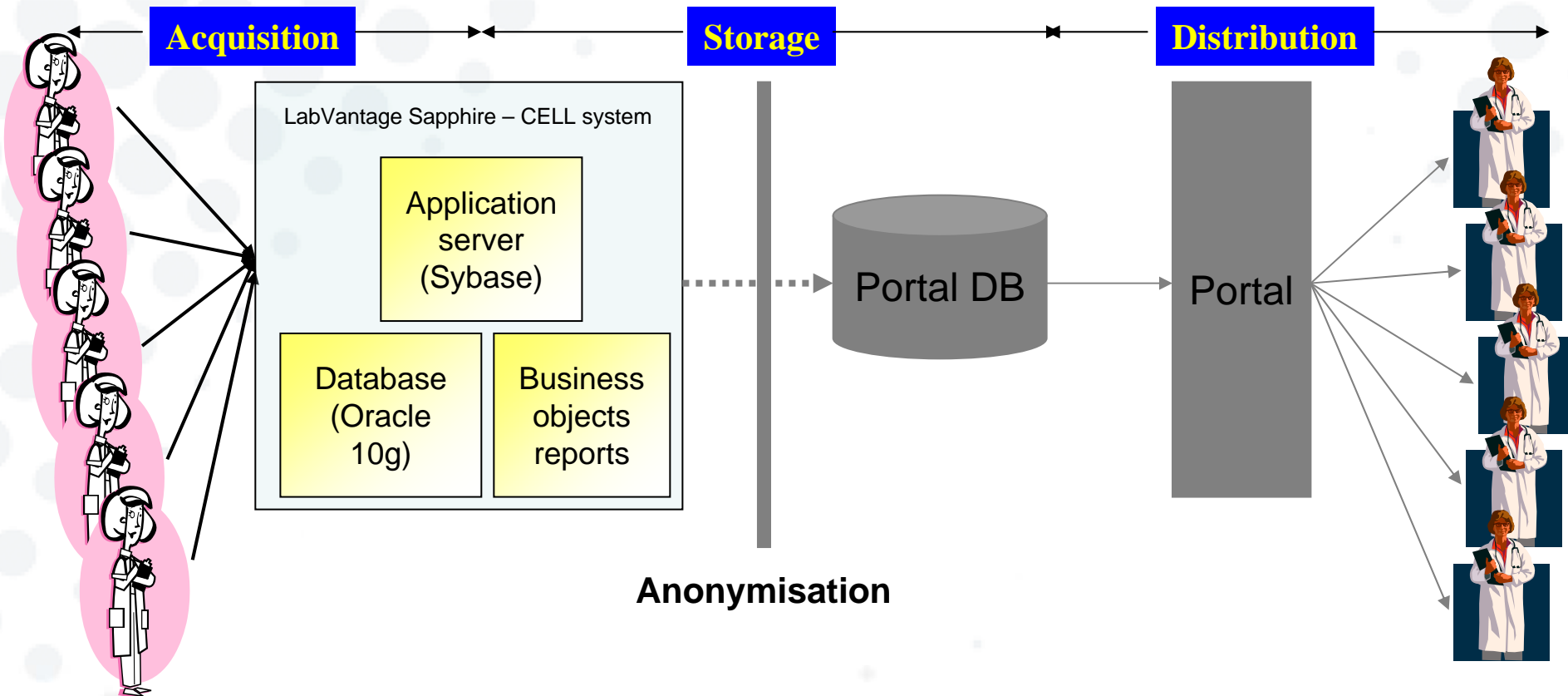
Inventory record management



System Design and Development



System Design and Development



- Initiated by onCore UK
- Organised and administered by the NCRI secretariat.
- Launched October 2006.
- Four founding members
 - Wales Cancer Bank
 - Tayside Tissue Bank
 - Glasgow Biobank
 - onCore UK
- Membership now expanded
- Will come to be the representative body for cancer biobanking in the UK.

CCB Members

CamUro-Onc Biorepository
Candis Cancer Tissue Bank Research Centre
Glasgow Biobank
Human Biomaterials Resource Centre
Northern Ireland Tumour Bank
onCore UK
Tayside Tissue Bank
UK DNA Banking Network
Wales Cancer Bank

NCRI Biobank Guiding Principles



http://www.ncri.org.uk/default.asp?sectionID=What_We_Do&pageID=Facilities_and_Resources&subPageID=CCB



Human Research Tissue Banks / Resources / Biobanks Guiding Principles

1. Introduction

- 1.1 This paper contains guiding principles applicable to the management and operation of a human biosample resource / bank in the ethical and legal environment of the UK from 2006 onwards. These are the guiding principles that underpin the National Cancer Research Institute's (NCRI) Confederation of Cancer Biobanks (CCB).
- 1.2 The organisations providing any of the services of procurement / acquisition, annotation / quality control, storage, cataloguing and distribution of human biological samples use various terminologies to describe themselves. These include bank, biobank, resource, repository, collection, archive, library and others. Similarly, many of these organisations use a variety of terms to describe the nature of the human biological samples that they obtain and provide. These include tissue, biosample, biospecimen, a specific disease term (e.g. cancer bank), a specific part of the body (e.g. brain bank, blood bank), an extract of the primary sample type (e.g. DNA bank), etc. The guiding principles in this paper can be applied to all such organisations irrespective of the terms applied.
- 1.3 The guiding principles contained in this paper are derived from a variety of sources. In particular, they reflect a composite of the views of several leaders of national not-for-profit human research biobanks from a number of countries, as represented by the group known as the Marble Arch Working Group. These views are also in keeping with opinions expressed in other publications and in other fora, both national and international, in recent years. However, to date there is no published consensus statement containing these principles from any group other than the NCRI CCB. The CCB wishes to promulgate these principles to build broad consensus within the wider community beyond the membership of the CCB.
- 1.4 Biobanks / biosample resources, etc are not isolated entities. They exist in an "ecosystem" or community of stakeholders that is diverse and includes the public, patients, healthcare workers, scientists, government, funders of science, providers of healthcare services, ethicists, regulators and others. Biobanks play a central role in the multidisciplinary "chain of supply" that extends from the donors through to the end-user researchers under the influence of the many stakeholders who interact with the supply chain. Each person or organisation interacting with the supply chain has a responsibility to adhere to common overall guiding principles and ensure that biosample supply is served and benefits realised.
- 1.5 The guiding principles proposed can be summed up by the responsibilities on all involved to maintain the **chains of trust, custodianship and benefit** along the supply chain for samples from donors to end-user researchers. In addition, such activities should be conducted with **consent** and under **cost-contribution financial models** for the onward provision of samples along the supply chain.

2. Biosample resources are for the public benefit

- 2.1 This may be summed up as the principle of maintaining the "chain of benefit".
- 2.2 Human research biosample resources only exist as a consequence of **sharing** - the altruistic act of donation by members of the public, who may be patients in a healthcare setting or healthy donors in other settings. These donations of samples are intended to further research into human health and disease.

V 6.0
01-11-06

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Tel: +44 (0)20 7061 8460 Fax: +44 (0)20 7061 8461
ccb@ncri.org.uk www.ncri.org.uk/ccb



Outline of the presentation

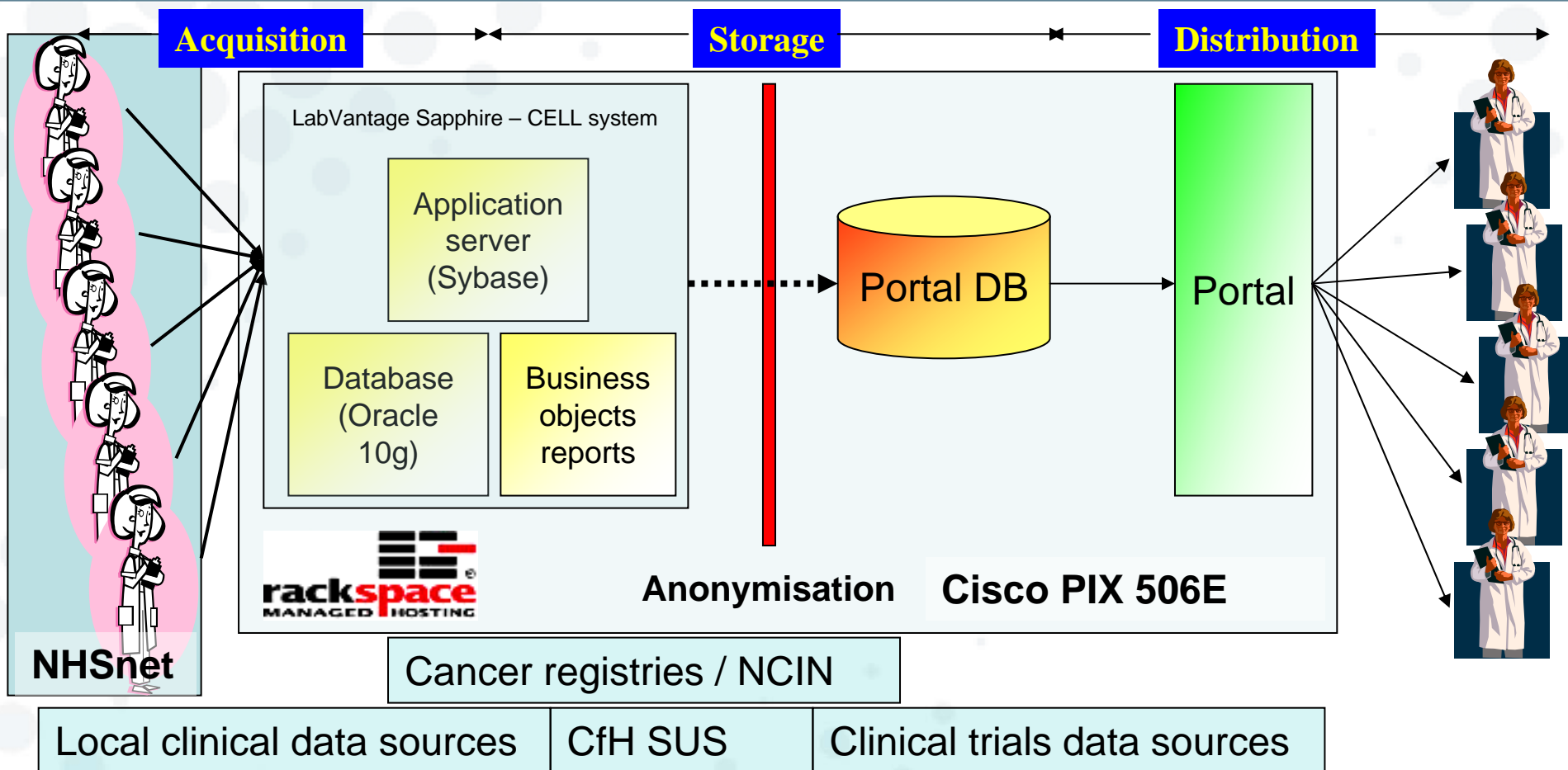
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Clinical Data Capture Channels

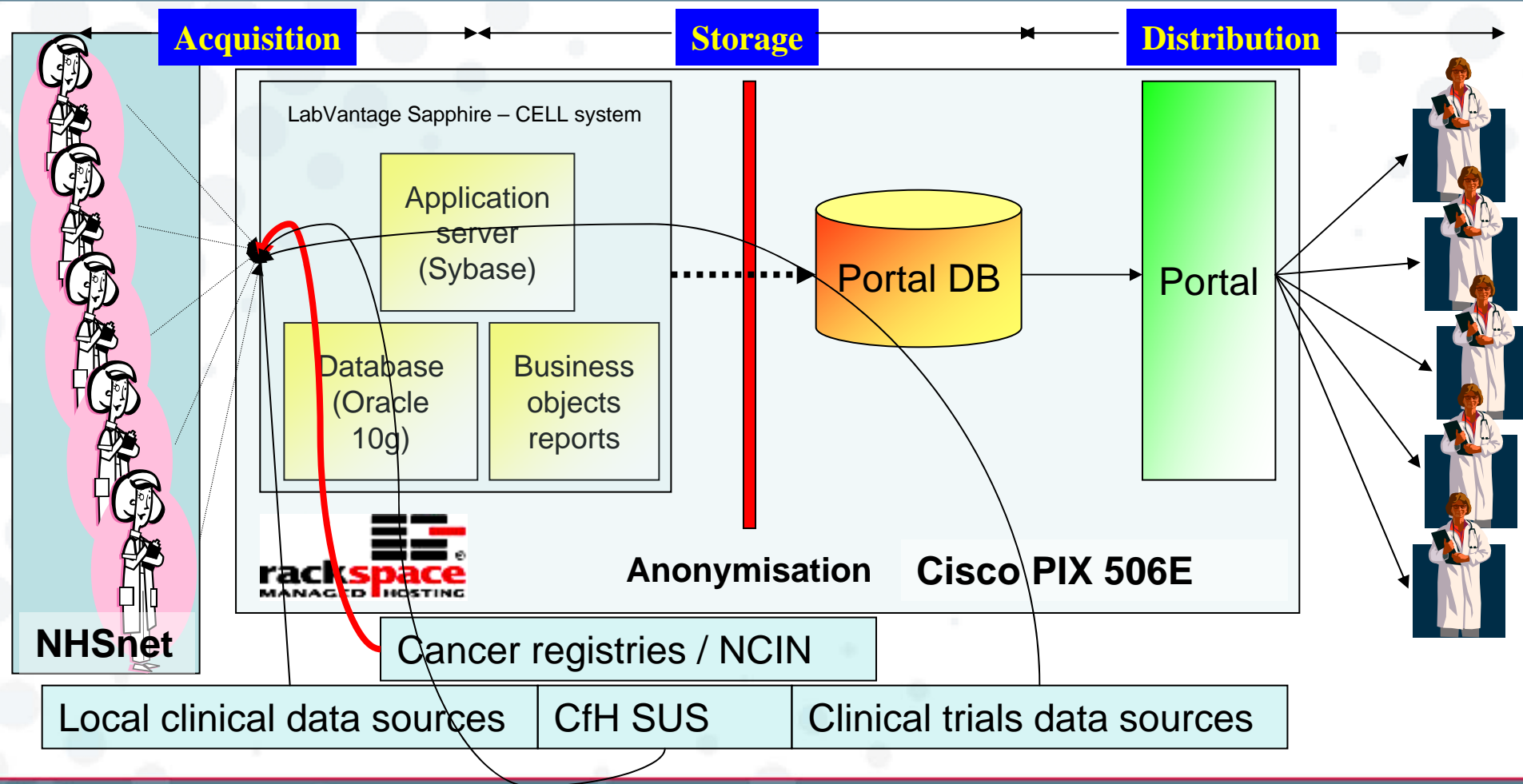
- **Multi-channel approach to ensuring ability to capture full picture.**
 - **onCore UK has started with manual data entry as first channel.**
 - Minimum number of fields obligatory – mostly to identify donor
 - Upload of scanned documents unstructured data possible.
 - **Data Exchange with Cancer Registries / NCIN as a second channel**
 - Automated file transfer from local clinical databases as third possible channel
 - Linkage to Clinical Trials Units?
 - NPfIT / Connecting for Health - “Secondary Users Service – Exchange Mart”??
- **Intention is to end up with very low, if any, duplication of effort.**



Clinical Data Capture Channels

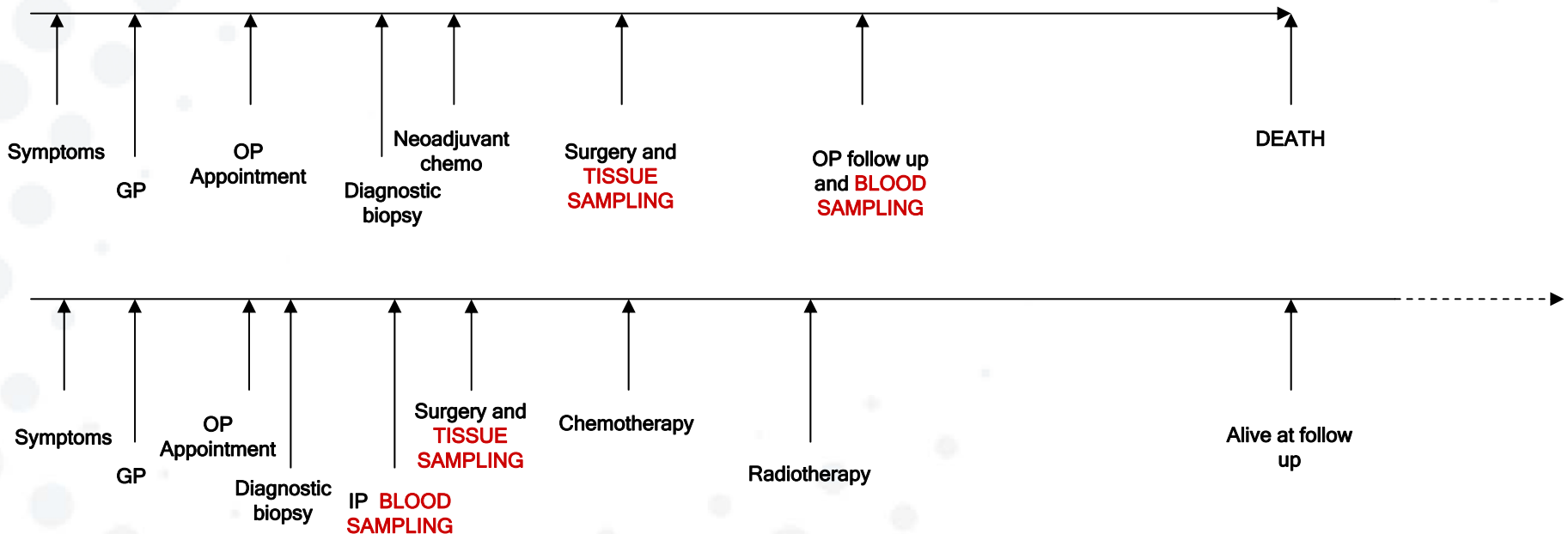


Clinical Data Capture Channels – future developments



Importance of Information for Biorepositories

- **A Biorepository without annotating data is like a Banquet without a menu!**



Importance of NCIN for Biorepositories

- Collect once, use many times – removal of duplication of effort, funding, interpretation, introduction of error,
- Unified source of *validated* baseline patient and clinical information, based on existing and routinely collected information.
- Source of longitudinal clinical data and episode statistics.
- Clarity and agreement on access to data and onward supply / use of data, security, confidentiality,
- Informatics interoperability.

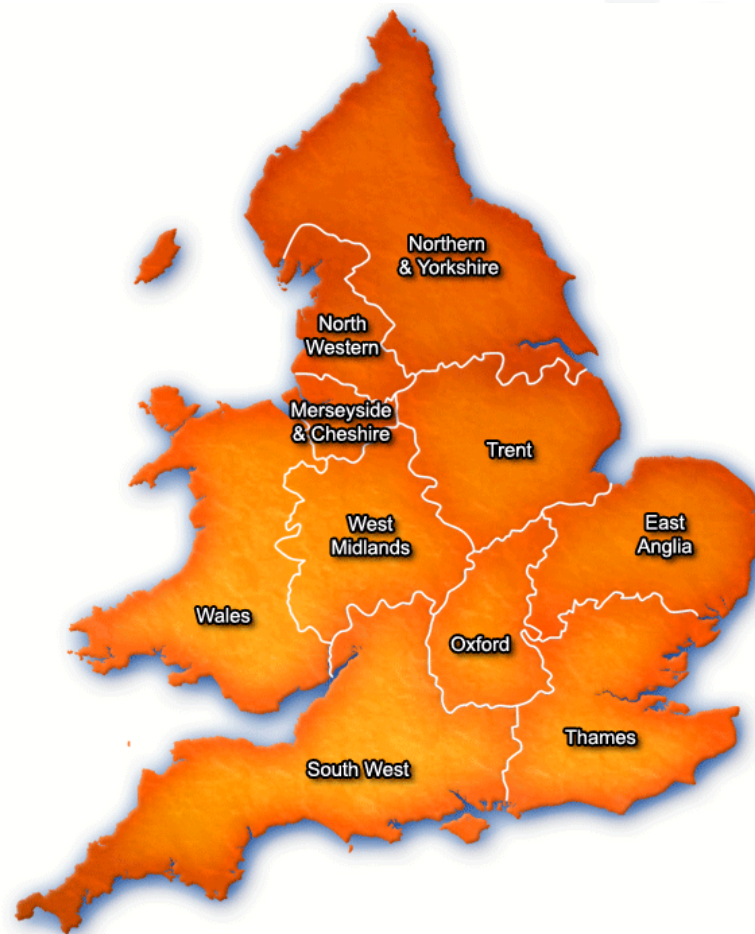


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Working with NCIN and Cancer Registries

- Our current sample acquisition is in the regions of the South West, Eastern and West Midlands Cancer Registries.
- Working with Tarik Malik and the Cancer Registration Team of the South West Public Health Repository to investigate regular data feeds.



Working with NCIN and NCRI – Access Working Group

- Working Group to explore issues related to access to human biosamples and data useful for research.
- Involves Jane Cope and Chris Carrigan.
- Chaired by William Lowrance.
- About to embark on a wide consultation of interested parties.
- Plan to produce a draft multipurpose and multi-scenario access policy around the end of 2008.

The challenge ahead is sharing...

- Samples
 - Information
 - Knowledge and expertise
 - Technologies
 - Opportunities
 - Risks
 - **Benefits of science for patients and societies**
-
- Timely convergence of priorities, policy, biology and technology.
 - We can't afford to miss this chance.

Contact me via

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● 0208 731 4591