

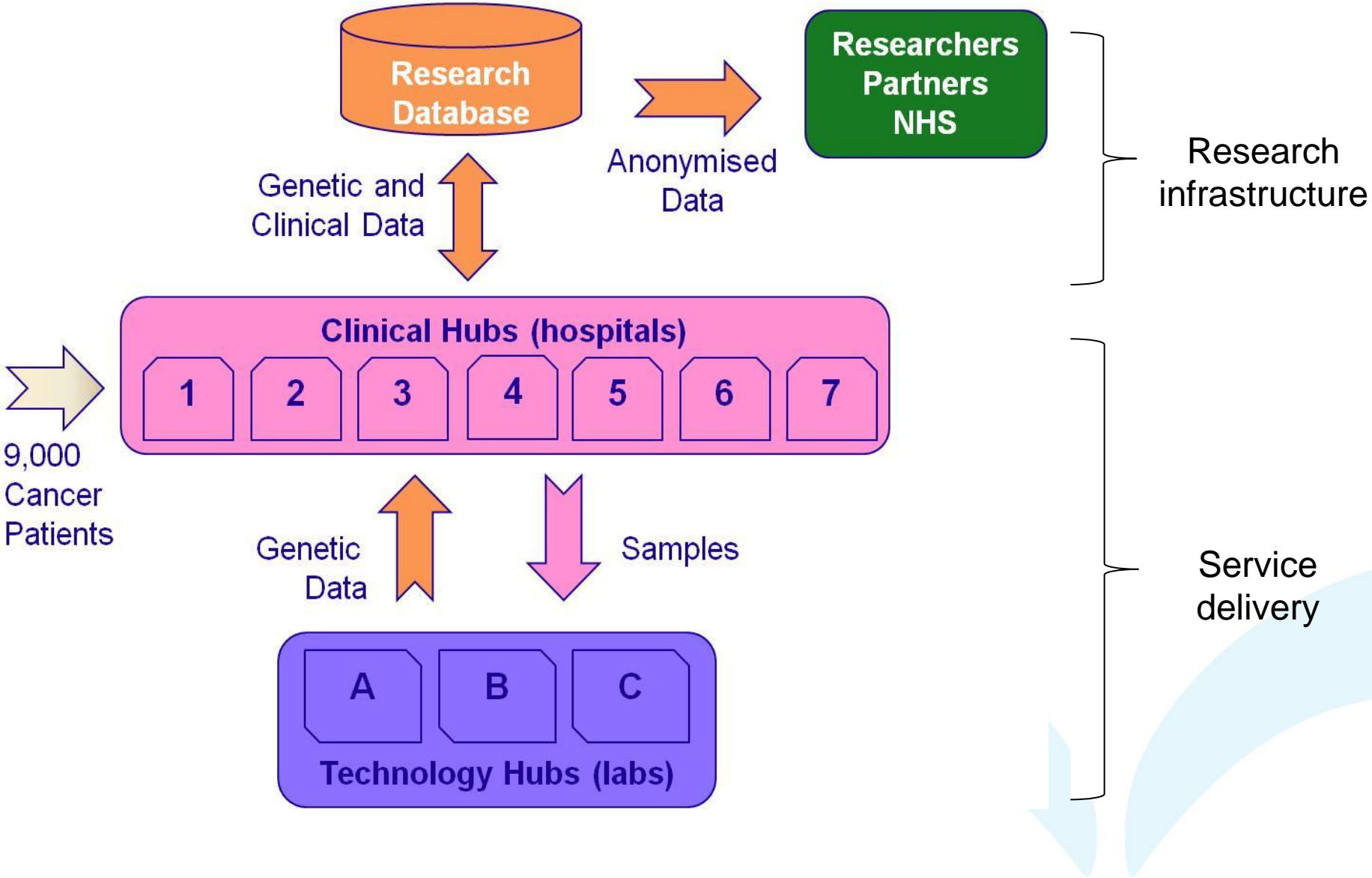
Stratified Medicine

Key exemplar project for Safe Haven

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NHS Greater Glasgow & Clyde**



CRUK Stratified Medicine Project



CRUK Stratified Medicine



- 6 Tumour types

Breast, metastatic melanoma, prostate, lung, colorectal and ovarian

- surplus tissue
- surplus blood (useful for genetics only)

Authorisation – surplus tissue

- **Information**
 - Develop generic A4 standard information sheet
- **Must cover**
 - future use that is broad & enduring
 - academic and commercial future uses
 - linkage to routine healthcare data
 - possible genetic analysis
 - possible return of information to NHS
- **Electronic approach**
 - to record authorisation
 - to ensure visibility (patient CHI in SCI store)

Information about The Use of Surplus Tissue for Medical Research & Education

We would like you to donate some of your tissues and body fluids for medical research and education. This leaflet will help you to decide if this is something you want to do. Please think about this and read the information carefully.

What is tissue?

The human body is made up of cells that form a large number of tissues. Sometimes the tissue makes organs like the lungs, liver or appendix. Other tissues do not form organs, for example bone and skin. Body fluids such as blood, urine and saliva also contain cells.

Doctors or other health care staff may take tissues, blood samples or body fluids as part of your care. For example, during surgery or when taking a blood sample for tests. They will send this tissue to a Pathologist to find out or confirm what is wrong with you. A Pathologist is a doctor who is an expert in examining tissue and body fluids.

The doctor will not take more tissue or body fluids than is needed for your care. But, if there is some tissue or body fluid left over that is not required for your diagnosis or treatment it could be used for medical research and education.

What happens to my tissue after diagnosis?

The Pathologist would normally keep some of your tissue as part of your medical record so that it can be examined again if you are ill in the future. In bigger operations and biopsies most of the tissue would not usually be kept. The NHS would like you to donate some of this surplus (left over) tissue for medical research and education.

Do I have to do this?

No. It is up to you to decide if you want to donate surplus tissue. Your decision will not affect your treatment, care or diagnosis. If you

decide to take part, you can change your mind at any time. You don't need to give a reason. When you arrive at the hospital a member of staff will ask you whether or not you wish to take part.

Why is human tissue required for research and education?

As well as providing care and treatment, the NHS is responsible for making sure that medical students, nurses and other healthcare professionals get the training they need.

Doctors and scientists also need human tissue for medical research. From it they can see and understand how a particular disease or problem starts and develops. They can also try out different drugs and tests on the tissue. They may find new medicines and treatments. They may also find ways of diagnosing a disease earlier.

Where will researchers or clinical teachers use my stored tissue?

- In the NHS
- At universities
- At research institutions
- At biotechnology companies (pharmaceutical companies)

Before using your tissue, all of the above must prove that they are following legal and ethical guidelines for their research.

All research studies will be approved and monitored by an independent regulatory body.

How long will tissue be stored?

The tissue you donate will remain in the NHS until it is all used or you withdraw your consent. However, if you change your mind after your operation, some of your tissue may already have been used for research.

Will my medical notes be used?

Yes. Researchers need to know the medical history of the person who donated the tissue. The NHS needs your permission to take this information from your medical notes. All information that is collected will be kept strictly confidential. Any information that is given to researchers will have your name and any other personal information removed so that you cannot be recognised from it.

Can researchers find new information about my health?

The research on your tissue will normally have nothing to do with your own care or treatment. If anything is found that you need to know your doctor will be told.

Will the researchers carry out genetic tests on my tissue?

It may be appropriate for genetic tests to be carried out. A lot of research today focuses on the study of genetic material from normal individuals and those with known diseases. This comparison helps to reveal genetic differences, which can then be used to develop future drugs and therapies. The results of these tests can not be traced back to you. Researchers will only use these test results for research and education.

Will anyone make money from my tissues?

It is illegal to sell tissue for profit. The NHS may charge researchers a fee for your tissue but this is to cover the costs of collection, preservation and storage of your tissue. The NHS uses a considerable amount of staff knowledge and skills ("know-how") to explain what is wrong with you. This "know-how" is valuable information for researchers. The NHS will use money it gets from researchers and your tissue to improve care to its patients.

If researchers develop a new drug, treatment or test, a pharmaceutical company or other researcher may then make a profit. It will not be possible for you to make a claim for money if you donated tissue. However, any new drug, treatment or test may help everyone in the future.

I'm still not sure if I want to take part.

If you need more information to make up your mind, talk to your doctor or nurse, or contact NHS Greater Glasgow & Clyde Bio-repository nursing staff on 0141 211 4531.

I want to donate ... what do I do next?

When you come into hospital or attend a clinic you will be asked if you agree to let your surplus tissue to be used for medical research. Your wishes will be recorded electronically.

I do not want my tissue to be used in research.

If you do not want your tissue to be used for medical research, then when you come into hospital or attend a clinic and we ask you to let us use your surplus tissue for medical research you can say no. We will record this electronically. Your decision will not affect your treatment, care or diagnosis.

Further Information

If you have any other questions then please contact: 0141 211 4531 or [www](http://www.nhs.uk)

If you would like this document in Braille or audio-tape format, please contact: 0141 211 4531

If you would like this document in another language, please contact: 0141 211 4531

Ma tha sibh ag iarraidh an fhiosrachaidh seo ann an cànan eile, cuiribh fios gu:

Jesi chcez uzyskać te informacje w innym języku skontaktuj się z: Eger bu bilginyi bir başka dilde istiyorsanız lütfen bağlantı kurunuz:

اگر آپ یہ معلومات کسی اور زبان میں حاصل کرنا چاہتے ہیں تو براہ کرم اپنی رابطہ کریں:
 मित्रों को इस विषय पर अधिक जानकारी के लिए कृपया हमें 0141 211 4531 पर संपर्क करें:

إذا رغبت في الحصول على هذه المعلومات بلغة أخرى، الرجاء الاتصال به:
 اگر این اطلاعات را به زبانی دیگر میخواهید لطفاً با این ادرس تماس بگیرید:
 如果您需要该信息的其它语言版本，请联系:

0141 211 4531

Acute Services Division

Diagnostics Directorate
Department of Pathology
Specialty: General Surgery



STA Form Release 1.0 RC 1.1

Hospital Name: Gartnavel General Hospital

Patient Details	GP Details
Name:	Name: COSTELLO, PAUL
Address:	Address: 1980 GREAT WESTERN ROAD GLASGOW G13 2SW
Postcode:	Telephone:
Correspondence Address1	
Correspondence Address2	
Correspondence Postcode	
Telephone:	Consent: Yes
CHI Number:	Sensitivity: Sensitive
CRN:	Consultant Name: MR. AITCHISON (AITC)
D.O.B:	Form Date: 07/04/2010
Sex: Male	

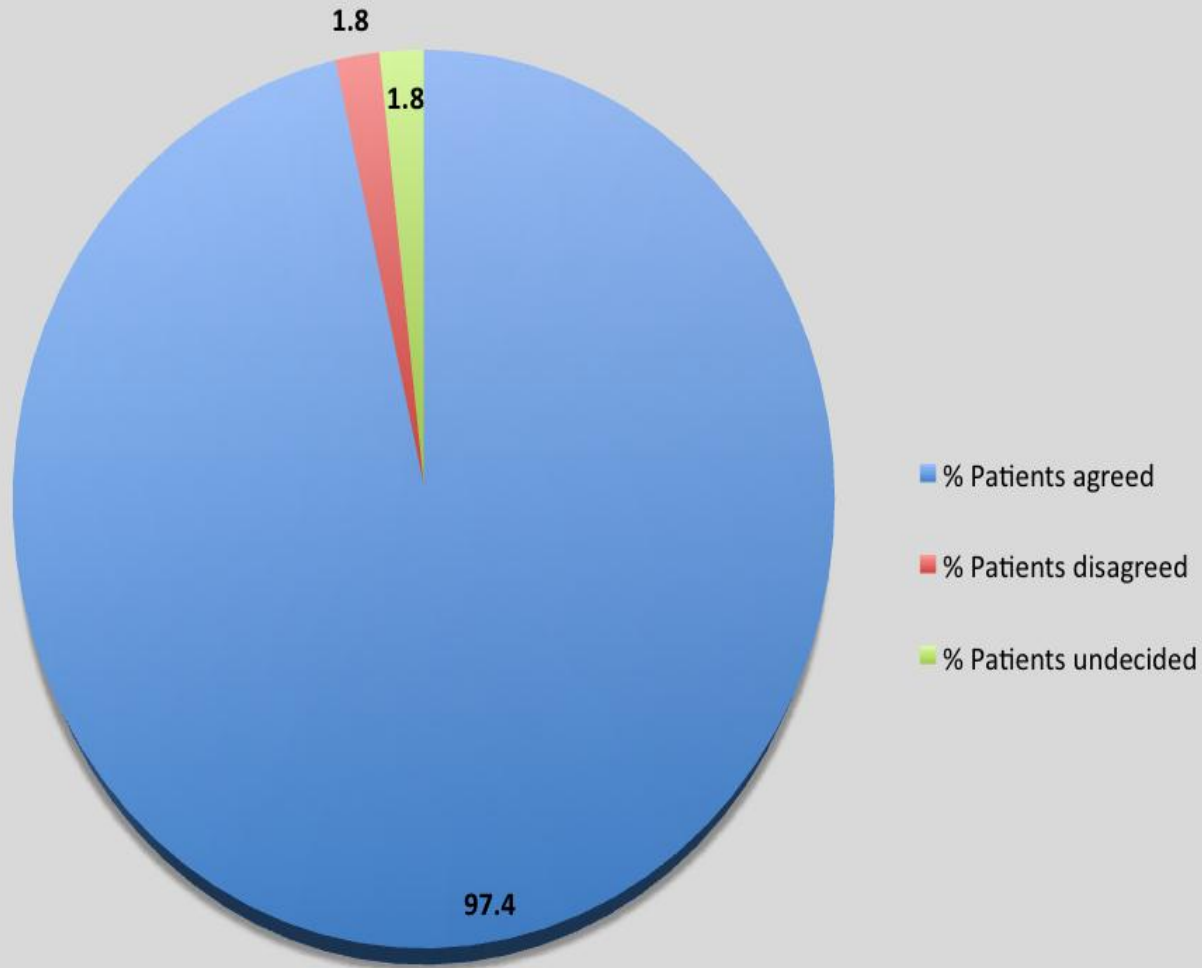
- | | Yes | No |
|--|----------------------------------|-----------------------|
| 1. Did you receive the patient leaflet "The Use of Surplus Tissue for Medical Research & Education"? | <input checked="" type="radio"/> | <input type="radio"/> |
| 2. Do you have any questions?
Questions:
Referred To Biorepository Nurses? | <input checked="" type="radio"/> | <input type="radio"/> |
| 3. Do you agree that surplus tissue not essential for your diagnosis or future treatment may be used for medical, education and ethically approved medical research? | <input checked="" type="radio"/> | <input type="radio"/> |

Withdrawal of Consent

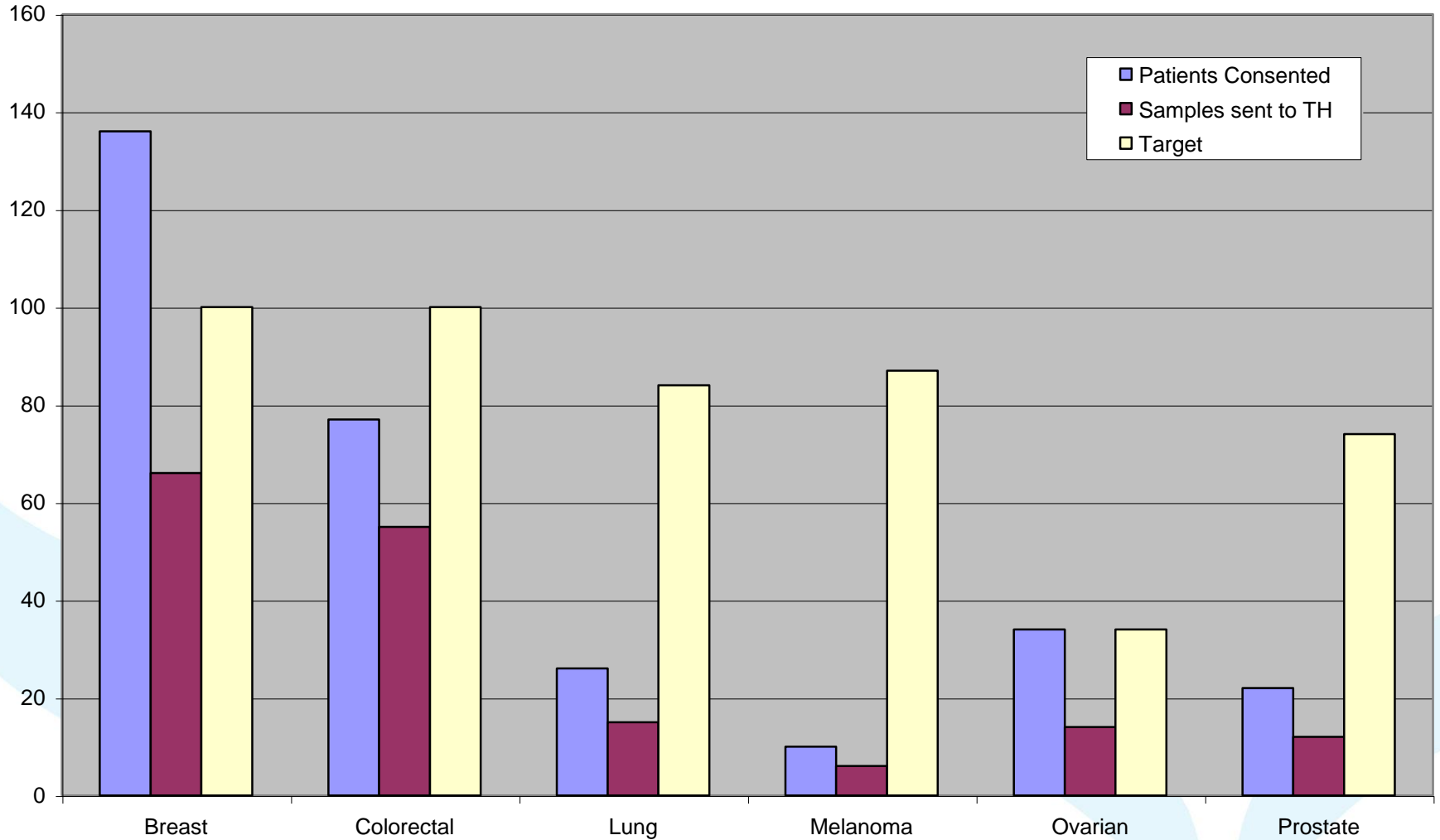
Date of Withdrawal

Comments

Audit of electronic process: 783 patients



Glasgow Clinical Hub - Tumour Type Breakdown



Evolution of NHS capability



- CRUK project ethics not required
- Amending PIS to explicitly cover paired samples
- Receipt of tumour specific information about key mutations measured – **research flag on clinical portal**
- Observational study – but already suggestions of open label trials based on mutation data
- Cancer – but applies to vascular, bronchoscopy or arthroplasty/arthroscopy tissue etc

Stratified Medicine - Genetic Cancer Research



Collecting 102 data items on 6 tumour types

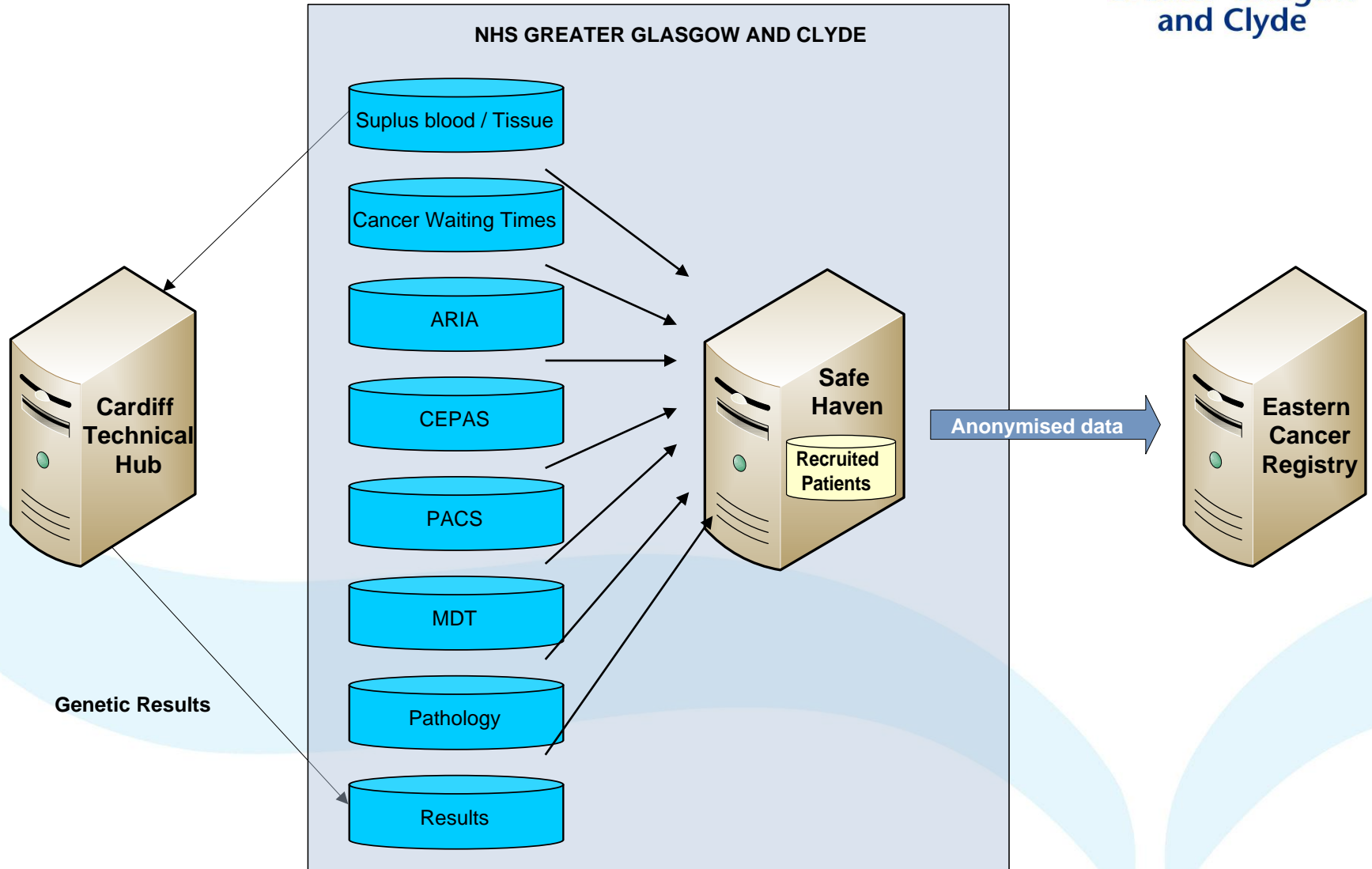
(Breast, melanoma, prostate, lung, colorectal and ovarian)

- **CWT**: Cancer waiting times – referral data
- **Aria**: Radiotherapy data
- **CEPAS**: Chemotherapy data
- **MDT**: Multi disciplinary team – Cancer care plan
- **Pathology**: Pathology of samples
- **Results**: Results of genetic tests carried out by technology hub

Surplus tissue and blood collected for genetic testing

Follow up for 3 years

Stratified Medicine



Barriers to data collection

- **Project based on English cancer dataset**
 - Scotland collects data based on individual cancers not one combined dataset therefore, it is not mandatory to collect all items
- **Different data definitions**
 - Fields within the various datasets may have the same name but definitions differ.
- **The MDT teams in GGC do not use any one system to collect data**
 - each of the MDT's collect data in their own way. This is not always electronically, therefore, manual data collection may be necessary for some fields.
- **Not all systems are managed by the HI&T department and therefore, permission to access their data had to be requested via various governance groups for these systems.**
 - This has resulted in a considerable delay in getting permission to access the data before we could even have a sample of the data to test whether it complied with the Stratified Medicine dataset.
- **Although pathology data is held electronically, it is in the form of a text report which does not allow extraction or analysis of specific data items.**
 - A new electronic system to collect the Pathology dataset has been developed which will automatically produce the xml file to send to the technical hub. The system will be able to generate reports, including an amendment report for pathology, which will allow the results from the technical hub to be sent back to the pathologist as an amendment to their original report held in our labs system.

Any Questions?