Todays tissue for tomorrows research

Ms. Clare Orange
Biorepository Manager
NHS GG&C Biorepository

Glasgow Biorepository

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Glasgow Biorepository

- Glasgow Bio-repository, set-up in 2002 is also one of the key operational units of the NHS Research Scotland (NRS) hub, funded by the Scottish Government Chief Scientist Office.
- The Biorepository is responsible for the governance associated with the collection, storage and use of all human tissues in NHSGGC and its affiliated organisations.
- The NHSGGC Biorepository is a unique service within the NHS. It provides a wide range of human tissue and bio molecular material for the medical research community (academia, research charities and industry).
- Applications made directly to the Biorepository and under delegated REC authority tissue is released to researchers for approved studies.
- The service is provided by various health care professional groups including Biomedical Scientists, Administrative and Clerical Staff, Healthcare Biomedical Support workers, IT staff and Research nursing staff

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NRS Biorepository Network

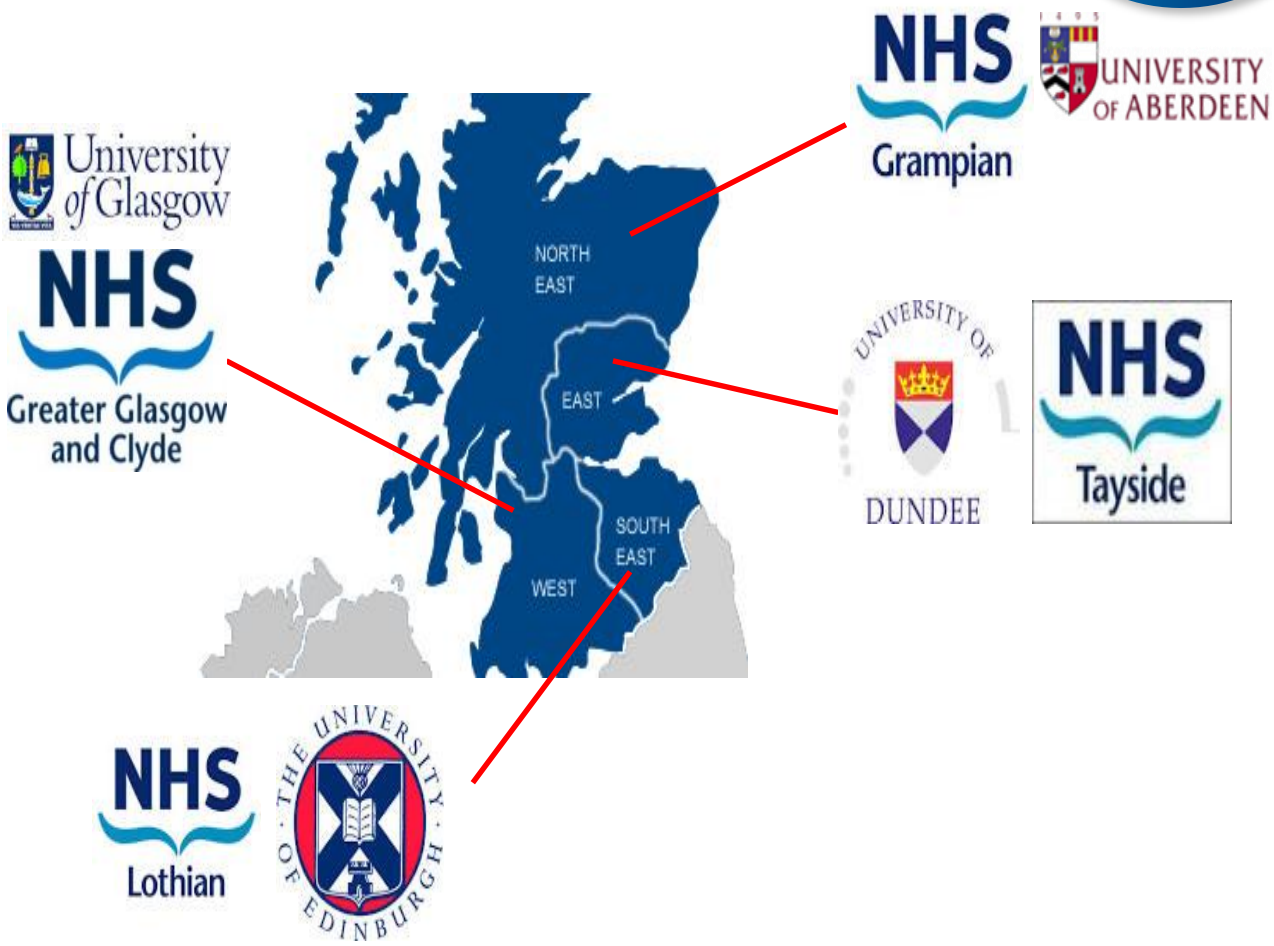
Responsibilities:

-Provide a robust, streamlined infrastructure to facilitate access to readily available human material for medical research and clinical trials.

-Create a structure for the governance of human tissue in Scotland.

-Facilitate the identification of material & collections held locally and if appropriate make available for approved research.

-Ensure that legal & ethical requirements are met for the collection, storage, use and disposal of human tissue.



Legislation

Human Tissue Act (2004) replaced the 1961 Act and included tissue from the living, transplantation, anatomy and public display

New Act had two main parts – consent and licensing.

2004 Act stipulates that it is appropriate and lawful to store and use relevant material for scheduled purposes provided appropriate consent is in place.

Human Tissue Act 2004

Human Tissue (Scotland) Act 2006 is consistent with legislation in England, Wales and Northern Ireland and covers –

Donation, primarily for transplantation
Research, education or training and audit
Removal, retention and use following a post mortem

Is based on authorisation rather than consent

<u>Does not cover use of tissue from the living</u>

Legislation

Human Tissue Act 2004	Human Tissue Act (Scotland) 2006
Consent is the fundamental principle of the legislation	Uses the term 'authorisation'
Different consent requirements apply when dealing with tissue from the deceased and the living. Removal, storage and use of relevant material from dead bodies Storage and use of relevant material from the living Under Common Law consent is needed for removal of tissue from the living	Provisions for the removal, retention and use of 'organs, tissue and tissue samples' **from the deceased**, for research. It does not regulate the use of tissue **from the living** for research. The Human Tissue (Scotland) Act 2006 states that authorisation is needed in order to remove and use post mortem tissue and tissue samples for research, unless they are Existing Holdings.
	Section 45 of 2004 Act on consent and DNA analysis implemented UK wide (including Scotland).

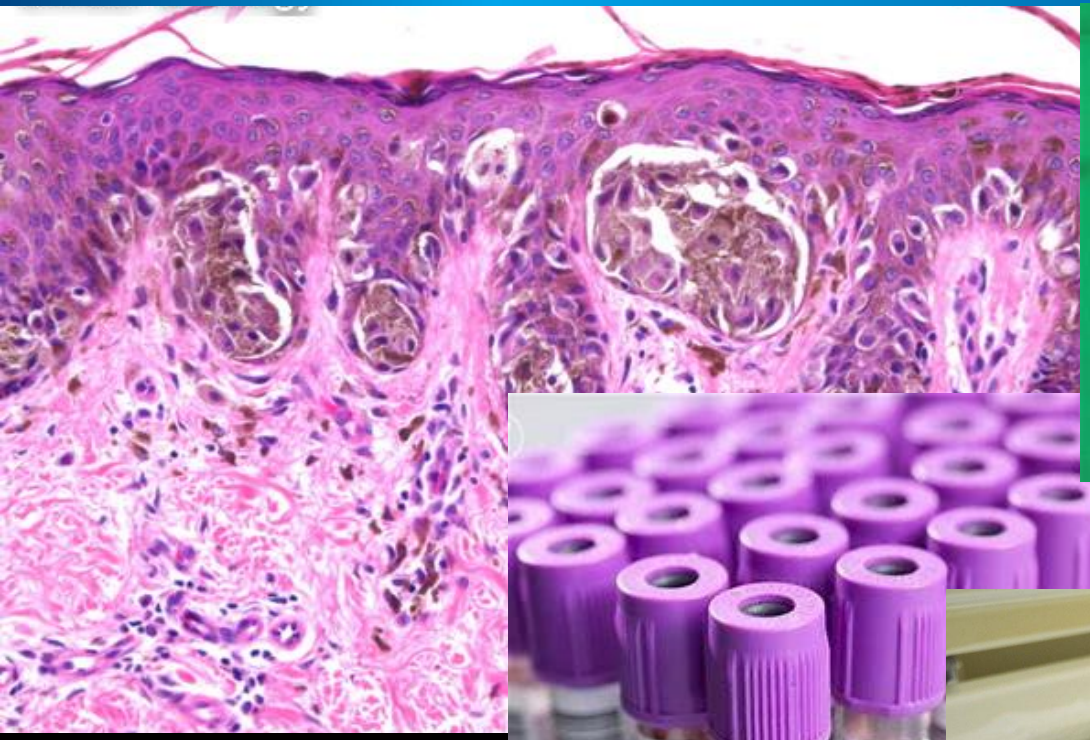
Accreditation

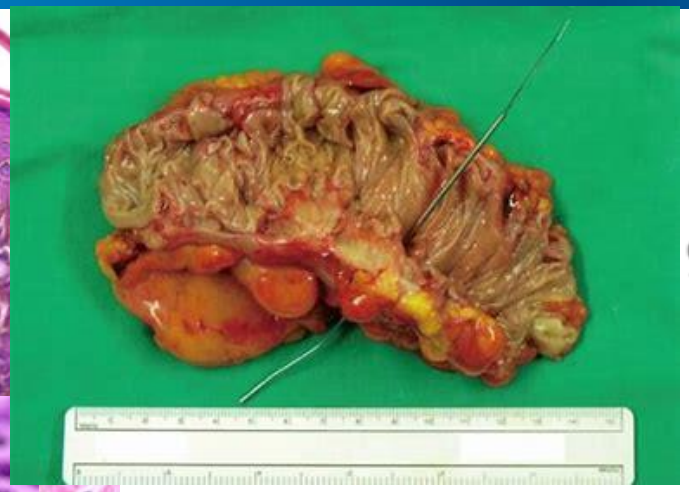
- In England, Wales and Northern Ireland Human Tissue Authority is the regulatory body that licenses uses of tissue from living or deceased for certain scheduled purposes
  - -anatomical examination
  - -establish efficacy of a drug or other treatment
  - -public display
  - -research in connection with disorders or function of human body

- Scotland 2006 Act does not have any regulatory authority.
- NRS Accreditation (est. 2011), reflects HTA standards – established to give framework for recognition of quality and governance in Scotland and reassurance to patients
- HTA does act as licensing authority in some instances in Scotland – Human Application (Therapeutic Tissue Banks (SNBTS) and ATMPS)

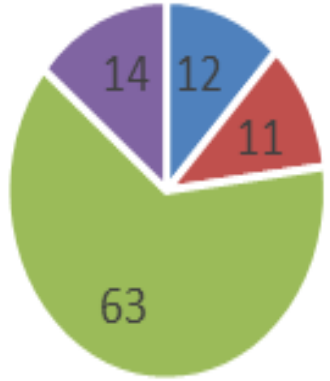
- In 2018, the new international standard for Biobanks was announced - ISO 20387.
- UKAS formed a steering group with experts from many different types of biobanks to assist in the development of accreditation and provide advice on the interpretation and application of ISO 20387 to the different types of Biobanks.
- They also established a pilot project for interested sites.

Biobanking in Scotland





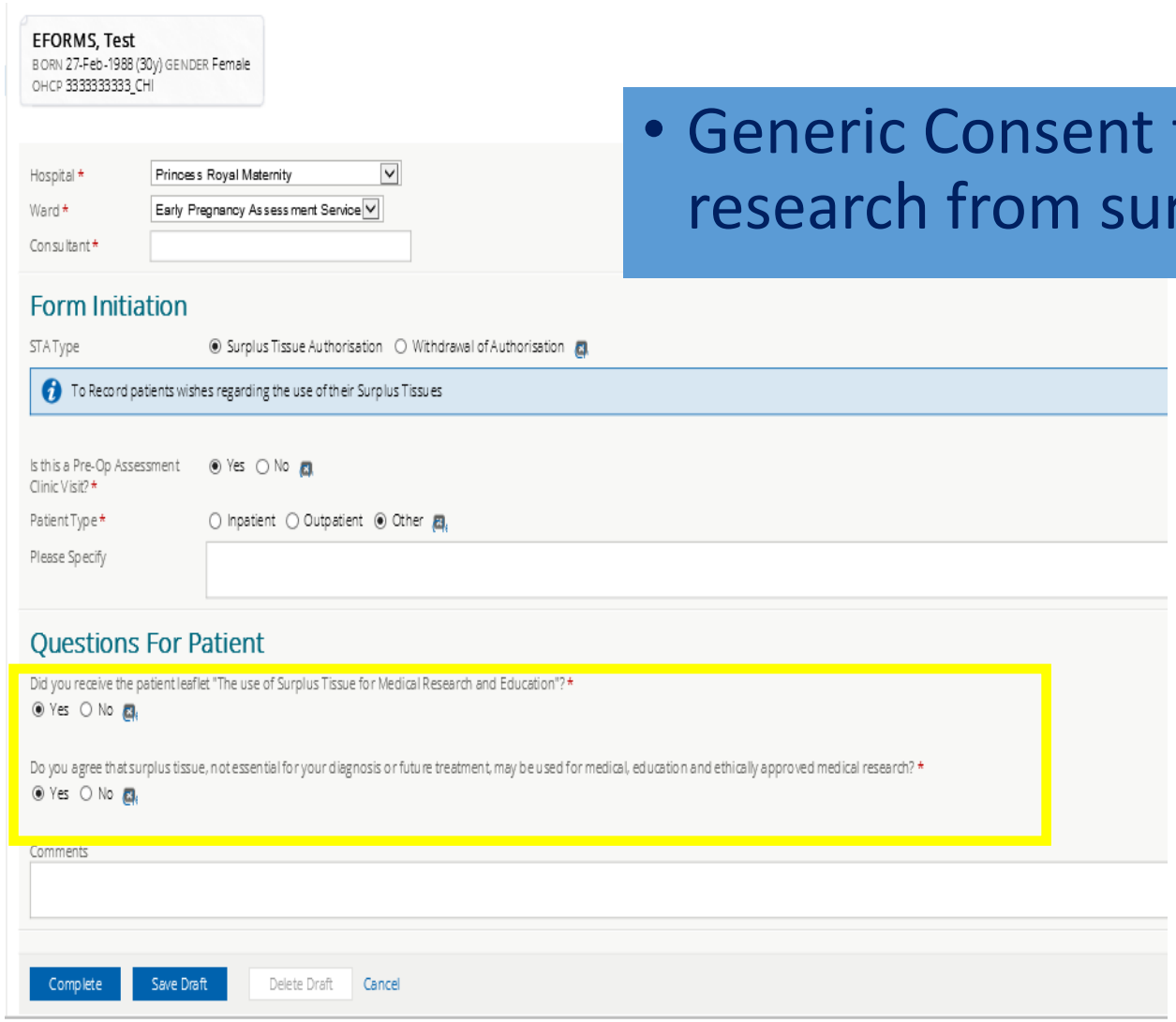
% of projects requiring different types of tissue



Fresh unprocessed
fresh frozen
Path archive FFPE
other

Biobanking in Scotland

- Generic Consent for tissue and images to be used in research from surplus to diagnosis or pathology archives



EFORMS, Test
BORN 27-Feb-1988 (30y) GENDER Female
OHCP 3333333333_CHI

Hospital * Princess Royal Maternity
Ward * Early Pregnancy Assessment Service
Consultant *

Form Initiation

STA Type: Surplus Tissue Authorisation / Withdrawal of Authorisation

To Record patients wishes regarding the use of their Surplus Tissues

Is this a Pre-Op Assessment Clinic Visit? * Yes / No

Patient Type * Inpatient / Outpatient / Other

Please Specify

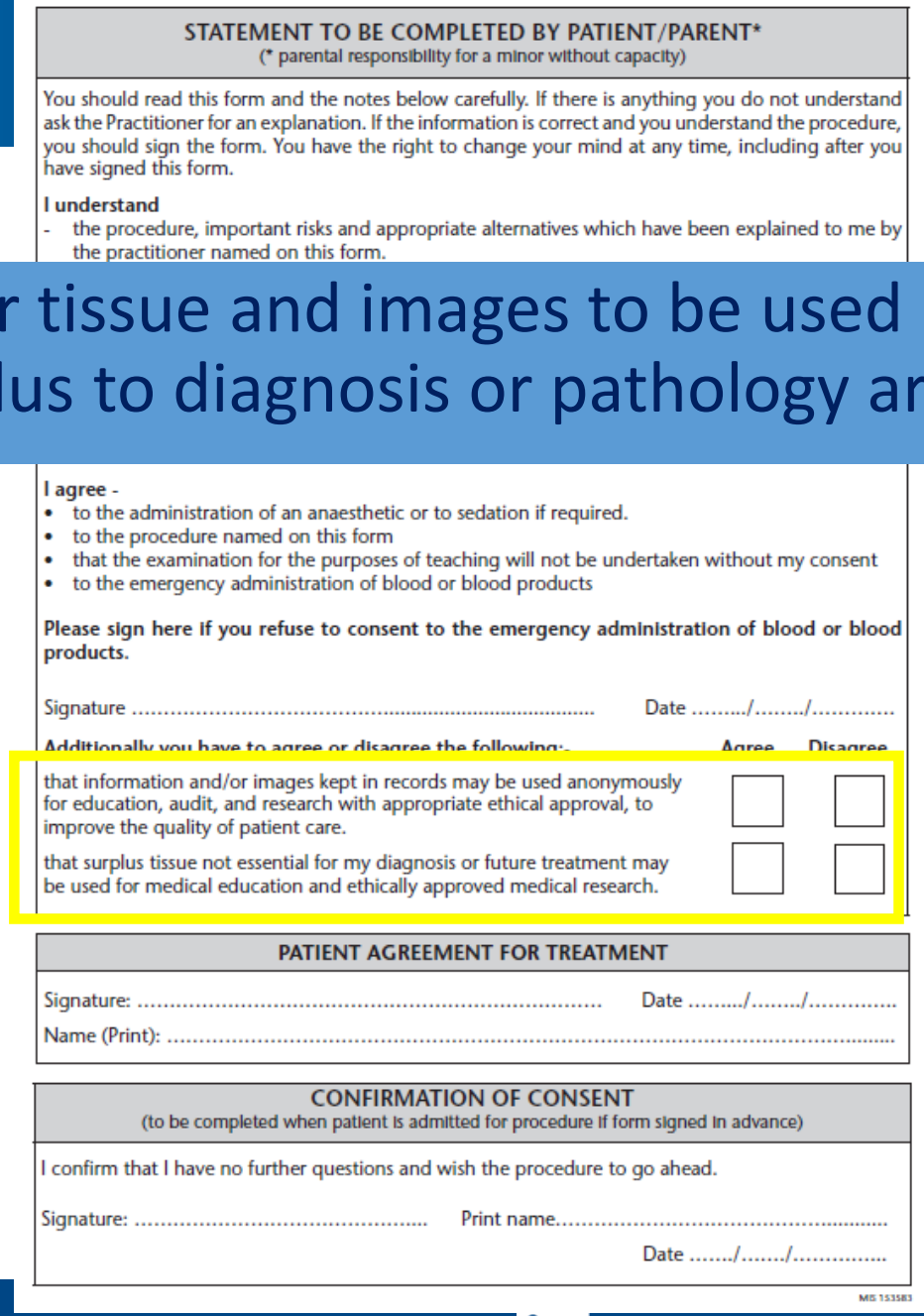
Questions For Patient

Did you receive the patient leaflet "The use of Surplus Tissue for Medical Research and Education"? * Yes / No

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? * Yes / No

Comments

Complete | Save Draft | Delete Draft | Cancel



STATEMENT TO BE COMPLETED BY PATIENT/PARENT*
(* parental responsibility for a minor without capacity)

You should read this form and the notes below carefully. If there is anything you do not understand ask the Practitioner for an explanation. If the information is correct and you understand the procedure, you should sign the form. You have the right to change your mind at any time, including after you have signed this form.

I understand
- the procedure, important risks and appropriate alternatives which have been explained to me by the practitioner named on this form.

I agree -
- to the administration of an anaesthetic or to sedation if required.
- to the procedure named on this form
- that the examination for the purposes of teaching will not be undertaken without my consent
- to the emergency administration of blood or blood products

Please sign here if you refuse to consent to the emergency administration of blood or blood products.

Signature ..... Date ...../...../.....

Additionally you have to agree or disagree the following:-	Agree	Disagree
that information and/or images kept in records may be used anonymously for education, audit, and research with appropriate ethical approval, to improve the quality of patient care.	☐	☐
that surplus tissue not essential for my diagnosis or future treatment may be used for medical education and ethically approved medical research.	☐	☐

PATIENT AGREEMENT FOR TREATMENT

Signature: ..... Date ...../...../.....
Name (Print): .....

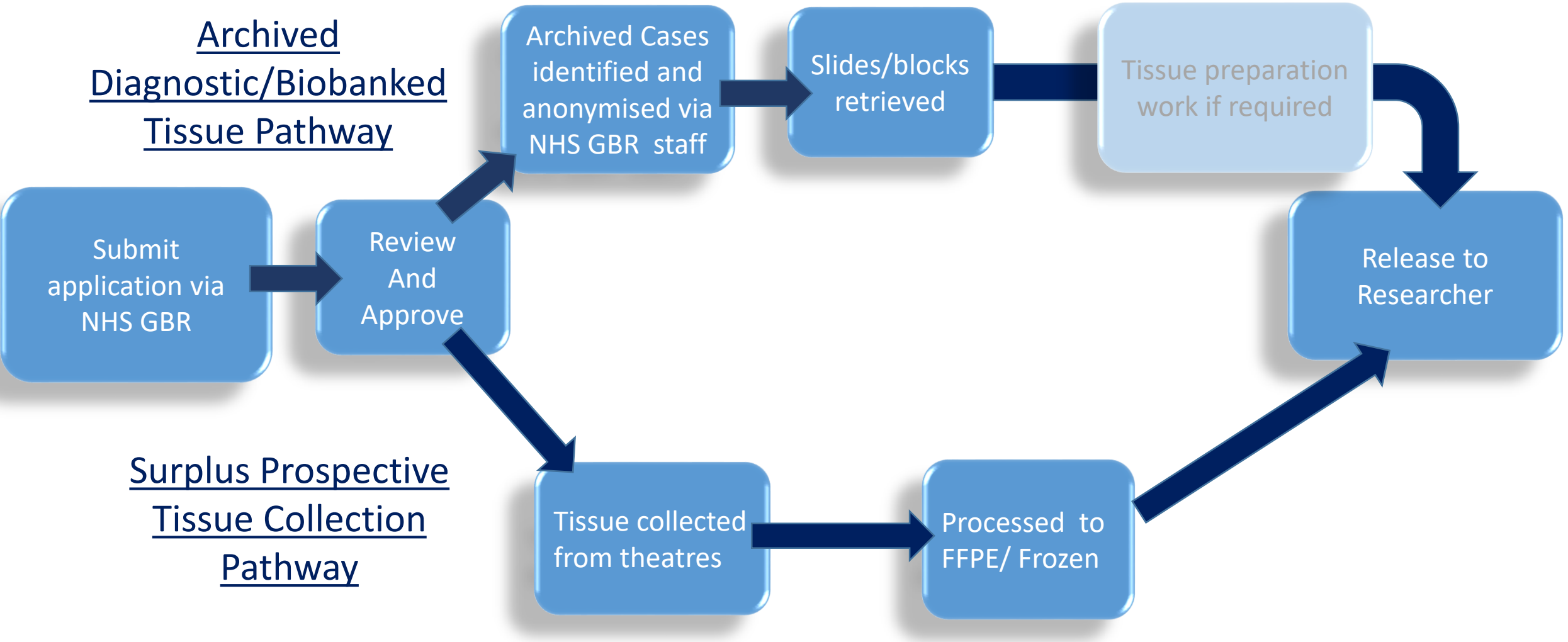
CONFIRMATION OF CONSENT
(to be completed when patient is admitted for procedure if form signed in advance)

I confirm that I have no further questions and wish the procedure to go ahead.

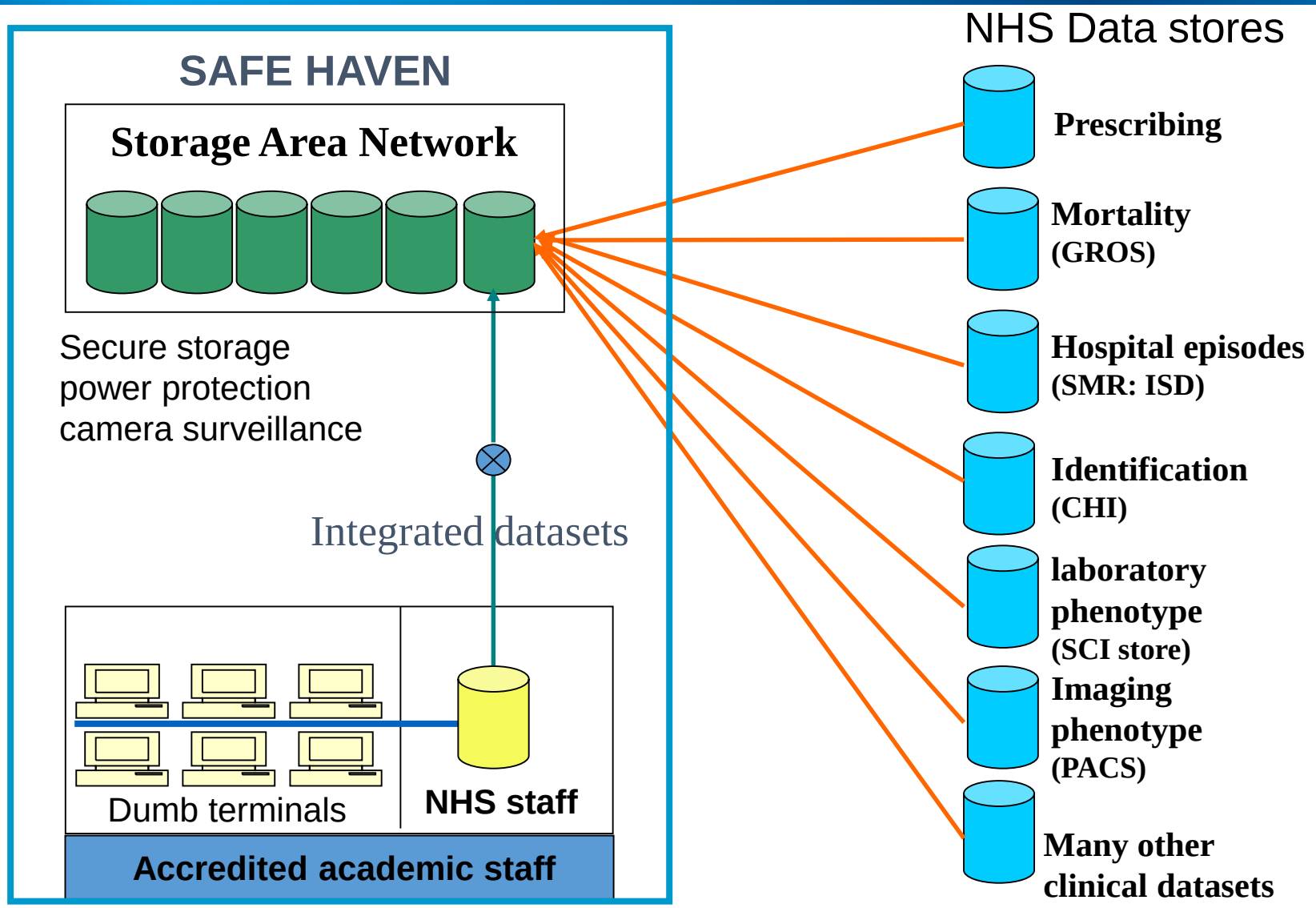
Signature: ..... Print name.....
Date ...../...../.....

MIS 153583

NHSGGC Biorepository



Safe Haven


SAFE HAVEN
Storage Area Network
Secure storage
power protection
camera surveillance
Integrated datasets
Dumb terminals
NHS staff
Accredited academic staff
NHS Data stores
Prescribing
Mortality
(GROS)
Hospital episodes
(SMR: ISD)
Identification
(CHI)
laboratory
phenotype
(SCI store)
Imaging
phenotype
(PACS)
Many other
clinical datasets

Guthrie Cards

- NHS Scotland has the largest and longest-standing collection (~3 million) of dried blood spots in the world. There is currently a moratorium on making this archive available for health research.

- As custodians of the blood spot cards the NHS GGC Biorepository reviewed and collated contents of New-born Screening archives ranging from 1965 to present day. New-born blood spots from consented Generation Scotland volunteers were retrieved, anonymised and sent samples to Edinburgh for DNA analysis.

- The study established the potential value of the blood spots archive for epidemiological and DNA-based biomarker studies.

- We shared the study findings with the Scottish Government Chief Scientist Office and they are planning a Public Consultation. This will then decide if research access should be allowed and if so, how that should be overseen and regulated.

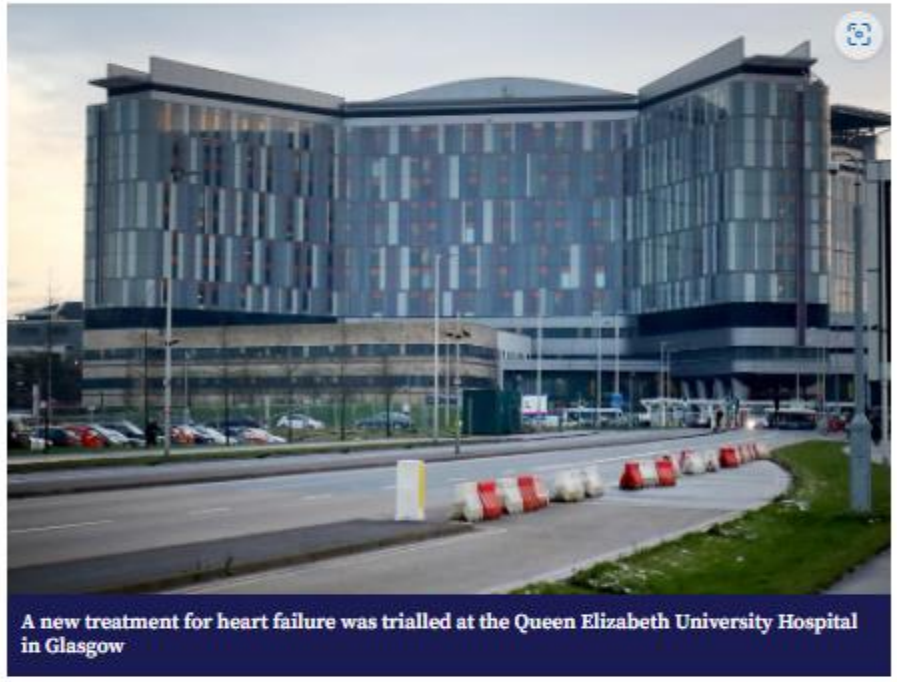
Cunningham-Burley, S., McCartney, D.L., Campbell, A. *et al.* Feasibility and ethics of using data from the Scottish new-born blood spot archive for research. *Commun Med* **2**, 126 (2022).

SUBCUT

Scots heart patients first in world to trial new treatment

1st October 2021

HEALTH GLASGOW



A new treatment for heart failure was trialled at the Queen Elizabeth University Hospital in Glasgow

By Caroline Wilson
Senior Reporter

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10 Comments

Patients with heart failure could soon be treated at home following a world-first NHS trial at a Scots hospital.

- The SUBCUT study helped researchers understand more about a new formulation of furosemide and a new dispensing pump and how we can use this to treat future patients.
- Heart failure is associated with frequent and lengthy hospitalisations. These hospitalisations are usually as a result of congestion, and the standard treatment of this is with intravenous furosemide - usually delivered in a hospital setting.
- The drug and pump were used to investigate the safety and tolerability of this novel infusor device in a home environment to see if an early supported discharge strategy would be possible where patients would be offered to use the new medication and the pump at home, instead of staying in the hospital for treatment given through a drip.

INCISE

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- The INCISE project - **IN**tegraged **T**e**C**hnologies for **I**mproved Polyp **S**urveillanc**E** – is a Glasgow University-led collaboration with NHS Greater Glasgow and Clyde, Canon Medical Research, BioClavis and OracleBio.

- The project aims to transform bowel cancer screening in the UK by developing a risk stratification tool which will predict polyp recurrence by utilising digital pathology, machine learning and next generation sequencing.

- Currently, patients who test positive for blood in their stool are invited for colonoscopy. Approximately 5% of those patients will have cancer whilst over 30% will have pre-cancerous polyps. These polyps are removed however, approximately half of those patients will go on to develop new polyps.

- INCISE identified a need to develop a more robust criteria for screening so that we are not subjecting individuals to frequent, unpleasant and invasive procedures that, in half the cases, are unnecessary. This will help to reduce surveillance lists and allow resources to be focused on higher risk patients.

Mansouri, D. , McSorley, S. T. , Park, J. H. , Orange, C., Horgan, P. G. , McMillan, D. C. and Edwards, J. (2021) The inflammatory microenvironment in screen-detected premalignant adenomatous polyps: early results from the integrated technologies for improved polyp surveillance (INCISE) project. *European Journal of Gastroenterology and Hepatology*, 33(7), pp. 983-989

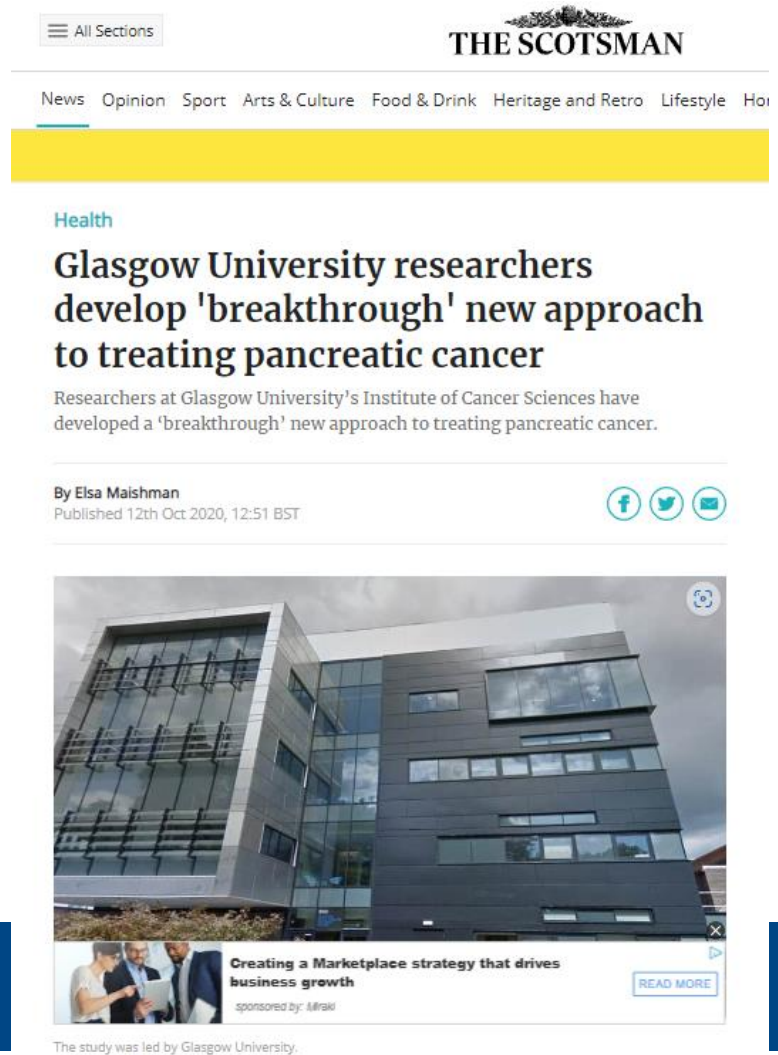
- Precision-Panc was founded in 2017

- With 10,000 patients diagnosed annually in the UK with pancreatic cancer (330,000 worldwide) and 9,300 deaths a year, **by 2025 pancreatic cancer is predicted to be the second most lethal cancer after lung cancer.** Pancreatic cancer is a very complex cancer with little in the way of effective treatments.

- Thanks to Precision-Panc there is now a UK wide network of over 20 hospitals that can offer precision medicine clinical trials to patients with pancreatic cancer.

- Precision-Panc Clinical Trials are delivered through the NHS and match people with pancreatic cancer to the trial most likely to work for them.

- Precision medicine clinical trials, based in the genomics of the patient and their tumour, offers hope for the 85% of pancreatic cancer patients who are not eligible for surgery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THE SCOTSMAN

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Health

Glasgow University researchers develop 'breakthrough' new approach to treating pancreatic cancer

Researchers at Glasgow University's Institute of Cancer Sciences have developed a 'breakthrough' new approach to treating pancreatic cancer.

By Elsa Maishman
Published 12th Oct 2020, 12:51 BST

Creating a Marketplace strategy that drives business growth

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The study was led by Glasgow University.

TILs studies

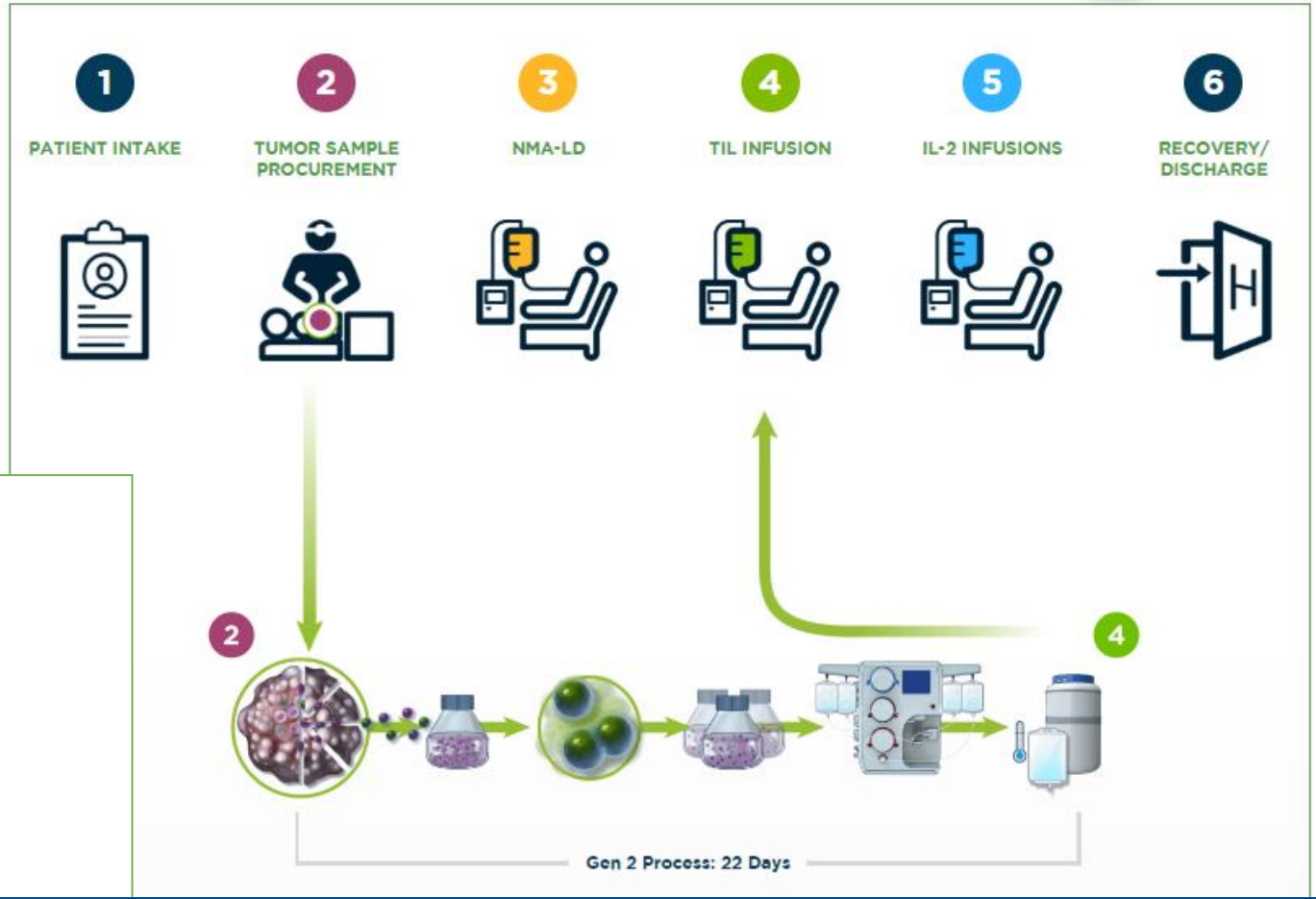
A patient's naturally occurring TIL are collected from a portion of their own tumour

These TILs are then activated and grown outside the body using a manufacturing process to produce a TIL therapy.

TIL therapy delivers these cells back to the patient.

Once inside the body the TIL therapy deploys billions of personalized, patient-specific TIL to recognize and target diverse cancer cells.

IOVANCE BIOTHERAPEUTICS



Iovance Biotherapeutics Initiates Biologics License Application (BLA) Submission for Lifileucel in Advanced Melanoma

PDF Version

First TIL Therapy BLA Submission Initiated with U.S. Food and Drug Administration

Complete BLA Submission on Track for Fourth Quarter 2022

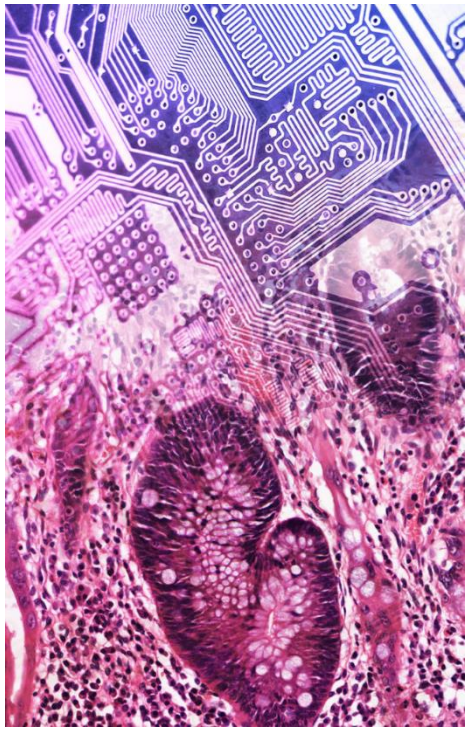
- **I**ndustrial **C**entre for **A**rtificial **I**ntelligence **R**esearch in **D**igital Diagnostics

  Programme established in 2018 and funded by Innovate UK Research programme that aimed to harness the power of AI at scale and look at applications to digital healthcare in radiology and pathology.

- By its close in March 2023 it had partners from across industry, the NHS, and academia with over 41 research projects.

- One of its major achievements has been the digitalisation of the pathology images which has transformed to transform the Pathology Laboratory at Queen Elizabeth University Hospital.

- Digital pathology and machine leaning based approaches offer the potential to generate precise reports and enable spatial analysis of large amounts of data. This may in turn enable the detection and grading of tumours and the development of new predictive scoring systems



SIREN Study

SARS-CoV2 Immunity & Reinfection Evaluation

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- Public Health England's SIREN (Sarscov2 Immunity & REinfection EvaluatioN) study is one of the national core studies established in response to COVID-19 and a National Institute for Health Research (NIHR) urgent priority study, providing vital research into immunity and vaccine effectiveness.

- SIREN is following around 40,000 healthcare workers over a 12-month period to investigate COVID-19 reinfection rates and immune response. As part of the study, participants are tested every two weeks, whether or not they have symptoms.

- By comparing the number of vaccinated participants with no previous infection who test positive for COVID-19 with the number of unvaccinated participants who receive a positive result, we can estimate how effective the vaccine is at preventing infection.

- SIREN showed that healthcare workers were 72% less likely to develop infection (with or without symptoms) after one dose of the vaccine, rising to 86% after the second dose.

PREDICT-Meso

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- PREDICT-Meso is an international network of researchers interested in the study of mesothelioma. Mesothelioma is preceded by decades of pleural inflammation providing a window of opportunity for precision prediction and early treatment.

- The PREDICT consortium hope to better understand how mesothelioma develops from its early stages and translate this into more effective diagnosis and treatment for patients.

- PREDICT-Meso carries out a range of basic and translational research studies to help improve our understanding of mesothelioma. These include genomics, epigenomics, transcriptomics, immune landscape, proteomics, breathomics, target drug validation and risk profiling.

- As part of its work PREDICT-Meso has set up a satellite research tissue bank under the governance of GG&C Biorepository. This is a tissue bank for mesothelioma tissue samples, images and data collected via PREDICT-Meso associated studies.

Kidd AC, Anderson O, Cowell GW, Weir AJ, Voisey JP, Evison M, Tsim S, Goatman KA, Blyth KG. Fully automated volumetric measurement of malignant pleural mesothelioma by deep learning AI: validation and comparison with modified RECIST response criteria. Thorax. 2022 Dec;77(12):1251-1259.

Thank you

Any Questions…..

Clare.Orange@ggc.scot.nhs.uk