WALES CANCER BIOBANK
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The Wales Cancer Biobank Strategy 2023-2028

CONTENTS

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Mission statement:

"To promote cancer research through leadership in the supply of biosamples, data and expertise to the international research community to drive innovation in Wales for the benefit of cancer patients globally."

Part 1: The Wales Cancer Biobank 2005-2022, a key resource for cancer research

Our core role as a cancer biobank

Patient donation of tumour samples is an essential component of a strong and vibrant cancer research infrastructure, bridging the gap between pre-clinical and clinical research. The availability of biosamples for researchers in Wales and the UK is fraught with logistical and regulatory challenges that hinder free and ready access of this important translational material.

The Wales Cancer Biobank (WCB) provides the infrastructure and expertise to overcome these challenges. It delivers consented and clinically annotated material in the form of fresh, frozen and fixed tissues and fluids from Welsh cancer patients to researchers within Wales and across the globe[1]. WCB has accumulated seventeen years' worth of experience, gaining an international reputation as a leader in the field of biobanking[2]. Its infrastructure provides unparalleled sourcing, processing and provision of cancer tissues to support cancer researchers in Wales.

Over 16,500 patients have consented to WCB collecting their samples and data since 2005 and just over half of these patient consents have been used in at least one research project, with one donation used in 11 different projects, spanning 11 years. 150 research groups across 9 countries have so far accessed samples, data and/or pathological images from its archive[1]. Additionally, WCB provides support to clinical trials collecting bio-samples for translational research by hosting samples and providing expert knowledge.

Our place in UK biobanking and the cancer research infrastructure within Wales

A recent survey undertaken by a group of international biobanks which was led by WCB revealed that WCB rates within the top 30% of participating cancer biobanks in the UK on the basis of the number of samples held and the number of research projects supported annually[3].

The benefits to the UK research community of dedicated cancer biobanks are many:

- Immediate access to NHS clinics and large volumes of samples and associated clinical data under one application/ethical process
    - Leading to reduced time and resource implications for researchers
- Consolidation of specialist expertise in sample handling, sample processing, regulatory and ethical issues

[1] For further details on WCB see our website: https://walescancerbank.com
[2] WCB was awarded UK Biobank of the Year 2020
[3] Parry-Jones et al., Manuscript in preparation for publication in 2023

- Well established links with NHS teams (cancer clinics) and related services (eg.genetics, histology, informatics)
    - Leading to quality assured processes that reduces research bias and increases confidence (of funders) in project outcomes and reproducibility
- Standardised biobanking practices ensuring services are fit for purpose and cutting edge
    - Providing researchers with access to wider resources, training, expertise and sample availability
- Established links with funders and regulators
    - Offering the ability to influence national and international biosample related agendas

WCB occupies an important place across the whole network of cancer research stakeholders in the UK and plays a key role in Wales (Figure 1), contributing to innovation in new cancer diagnostics and treatments that align with the ***Wales Cancer Research Strategy (CReSt)***[4].

WCB is independent of individual academic research groups, commercial interests and NHS Trusts, and so provides impartial access to clinical samples and offers expertise in sample collection and processing without favour. ***A dedicated biobank infrastructure with the associated approvals and specialist staff allows researchers to focus on the science and not spend valuable time and resource on regulatory requirements, ethics approvals and sample and data collection***. Funders and other stakeholders, especially patients, have the assurance that a professional biobank maintains the highest standards and, that the samples and data will be well curated, fit for the intended purpose and made widely available for cutting edge cancer research, wherever that takes place.

With its activity spanning NHS and academia, ***WCB provides an important link between clinical and pre-clinical researchers acting as a conduit for knowledge transfer, samples and data and thus promoting translational research***. WCB also provides an additional route for industry engagement and inward investment in cancer research in Wales.

WCB curates its own clinical and digital pathology databases, sourced from the NHS clinical portal and SAIL research database. ***This provides researchers with access to anonymised clinical data under its own ethics with associated digital histology which are important attributes of a forward-looking biobank.***

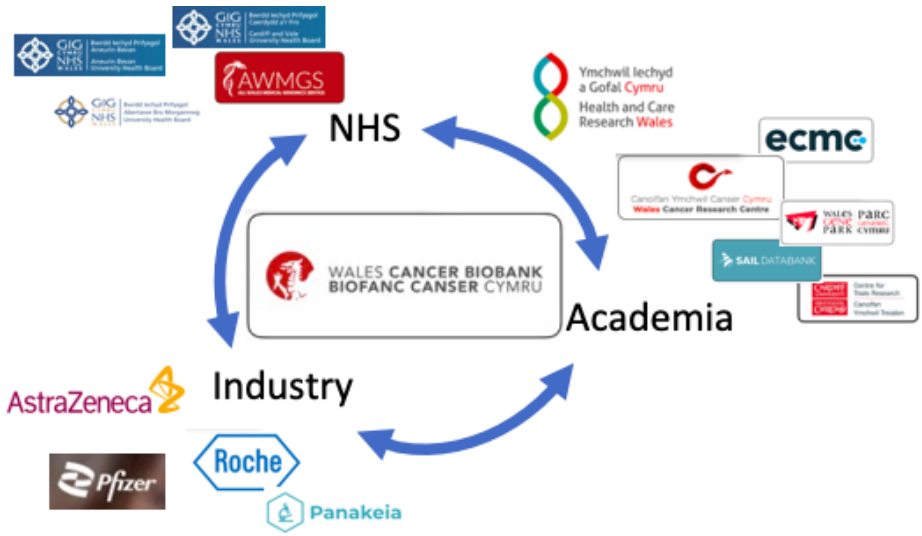


Figure 1: WCB's core activity of moving samples and data from the clinic to researchers means that it acts as a conduit between the NHS, academia and industry, supporting and promoting collaboration between cancer researchers in a variety of professional organisations and infrastructures

[4] https://walescancerresearchcentre.org/crest/

Part 2: The Wales Cancer Biobank 2023-2028, enabling future cancer research

"A new strategy to meet the changing needs of cancer research globally and to promote innovation in Wales"

The cancer research landscape is constantly evolving – never more so than during the recent explosion of genomic and digital technologies impacting on recent advances in our understanding of cancer biology and leading to improvements in diagnostics and targeted treatments. Wales needs an agile biobanking infrastructure that quickly adapts to changing researcher needs and which, in collaboration with its partners, can lead and inform on new innovations in cancer treatment and diagnosis. By providing this infrastructure WCB will be a key enabler for delivery of the new Cancer Research Strategy for Wales (CReSt) as well as an important partner in wider UK and EU cancer research networks.

WCB's previous 5-year strategy focused on achieving improvements in its sample delivery pipeline - transitioning from a 'savings bank' to a 'lending bank' – and increasing the scope of its services. All its stated short-term and mid-term objectives in these areas for the period 2020-2025 have been met or are on target[5].

Given that so much has already been achieved, and given the rapid changes in cancer research technologies, it is wise to build on this momentum quicky, and so a new research strategy is timely. This will build on the WCB's leadership, reputation, collaborations and resources and will ensure that the bank remains at the heart of the evolving cancer research landscape, and delivers growing impact in cancer research for the benefit of patients in Wales while also expanding its reach to the cancer research community across the UK and internationally.

This will be achieved by:

- ensuring progress on performance and sample supply; while
- deepening partnership and engagement work with patients and cancer research partners; and
- enhance existing and foster new links between academic, NHS and industrial cancer research stakeholders.

[5] As outlined in our annual stakeholder reports – go to: https://walescancerbank.com/stakeholder-report-2021-22/

WCB Core Strategic Pillars

WCB's strategy for delivering impact in cancer research in the next 5 years will be based on the following updated version of our existing four core pillars. In each case we will seek clear metrics to audit progress and ensure delivery of our objectives.

Performance

We aim to ensure our core biobanking activity[6] meets the changing needs of cancer research and aligns with CReSt priority areas

People

We seek to increase patients' opportunities to be involved in cancer research and to foster the development of the next generation of cancer researchers in Wales

Partnership

We plan to use our expertise through collaboration and leadership to accelerate innovation in cancer research, diagnosis and treatment

Promotion

We aspire to maximise the potential of WCB resources and expertise by expanding our network of stakeholders and partners in Wales and internationally

[6] We define our core biobanking activity as the provision of unfettered access to patient samples and data to the research community

WCB Strategic Aims

Our main strategic aims, which are predicated on the four strategic pillars described above, will focus on:

- *Increasing **Engagement** with our research stakeholders*
- ***Embedding** WCB activity within new and existing cancer infrastructures in Wales*
- ***Expanding** the reach and impact of WCB on cancer research across the UK and beyond*

Through these aims our aspiration is to promote cancer research activity and critical mass in Wales and to broaden our impact more widely across the UK and international cancer research communities. We will provide expertise and a leadership role in delivering the ***CReSt priority areas*** through direct involvement in the Wales Cancer Research Centre (WCRC) CReSt priority theme leadership groups alongside other cancer infrastructure partners. This will be in conjunction with our role in promoting the 'big cancer data' agenda through engagement with these research partners.

WCB will maintain and further enhance its strong public identity, demonstrating public service in cancer research in the most tangible way through the donation of Welsh patient samples for cancer research.

WCB recognises the importance of maintaining a lean and efficient operating infrastructure that provides both impact and value for money – while also remaining relevant to the needs of the research community. Ethical biobanking is a matter of national and scientific infrastructure and is not a purely commercial model anywhere in the world. Nonetheless we are committed to identifying a more sustainable funding model, which includes additional income based on fees for service; joint/collaborative research grant income; new infrastructure partnerships; and WCB-led research. This approach is built into our strategic objectives described below.

Our ***strategic aims*** are as follows:

- ***Meeting researcher needs for patient donated tissues***.
  Continue to advance our core function of consenting, collecting, storing and issuing quality-controlled biosamples for research across the UK and internationally.
  Embed WCB practices within each of the CReSt priority areas to help achieve ground-breaking innovations in cancer research within Wales.
  Drive forward state-of-art cancer research by ensuring WCB proactively plans for changing biosample and cancer data requirements.

- ***Informing and promoting new cancer research***.
  Using our biosample expertise to partner on new proposals for cancer research – providing expertise, infrastructure, research capability and patient and public involvement in ground-breaking new research applications.
  Empower Wales-based researchers and clinicians to take part in translational research activity by promoting unfettered access to biosamples.
  Underpin and enable translational and reverse-translational research in the six CReSt priority themes.

- ***Supporting the -omics data revolution in cancer research***.
  Ensuring our biosample and clinical database expertise shapes collaborative work between data infrastructures from academia, NHS and Industry to promote digital pathology, AI and 'big cancer data' projects.

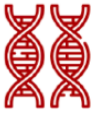
- ***Investing in People***.
  Investing in training and development of future leaders in cancer research and biobanking expertise in Wales. Providing inclusive opportunities for patients to take part in research studies, through sample donation and cohort-based questionnaires. We will reach out to more Health Boards and Trusts in Wales than currently to increase equity of opportunity for patients to donate their samples/be involved in research.

- ***Leading the Biobanking agenda.***
  Increasing the reach of WCB to improve sample usage. Strengthening UK/International biobank networks to increase international research opportunities. Improve outreach and marketing to stakeholders, including industry.

WCB Key Objectives

There are 7 cross-cutting Objectives that will help WCB to deliver on its Strategic Aims outlined above. These Objectives are predicated on the ***Wales Cancer Research Strategy (CReSt)***, launched in 2022 by Health and Care Research Wales, the Wales Cancer Network and key cancer research stakeholders in Wales to provide a unifying strategy around which the cancer community will focus its research activity in Wales. WCB is recognised as a key infrastructure partner in this endeavour and is ideally placed to influence the cancer research agenda and its delivery within this strategy.

Delivering on CReSt priority themes. WCB will engage with and support the Wales Cancer Research Centre to ensure that its biosample and data expertise is used to advance research in each of the six CReSt priority themes, as summarised below.



CReSt Theme 1:
Precision and mechanistic Oncology

Linking biosamples with -omics and clinical data has great potential for precision and mechanistic oncology research. Moreover, there is an increasing need for fresh and longitudinal patient material for pre-clinical and translational studies including organoids, circulating tumour cells and longitudinal samples collected during treatment. WCB is well placed to provide these resources in a way that removes the logistical obstacles for researchers and promotes engagement with industry partners. WCB will work with its existing partner infrastructures in the NHS and academia (eg. AWMGS, WGP) in the –omics space to deliver solutions for multiparametric data linkage and will help in developing new partnerships with pre-clinical and clinical researchers with complementary expertise, to exploit these new opportunities through joint ventures and external funding proposals.

CReSt Theme 2:
Immuno-oncology

WCB will work with our Welsh academic research partners particularly in Welsh universities, to bridge the gap between expertise in basic immunology / cancer models and clinical research in immunotherapy through the provision of patient derived tumour and tumour-associated tissues. This will help support links between basic and clinical research projects, promoting the development of new models to test cellular and viral therapies and to source exosomes and other biomarkers for novel diagnostics. We will expand on existing WCB-associated research projects based at Velindre Cancer Centre and Cardiff University, focussing on longitudinal sampling of patients receiving existing and novel therapies to investigate mechanisms underlying treatment relapse, sensitivity and toxicity.

CReSt Theme 3:
Radiotherapy

WCB will provide state-of-art biosampling (eg. longitudinal samples and ctDNAs from blood biopsies from patients undergoing radiotherapy) for cross-cutting research to inform new discoveries in radiotherapy prognostics and diagnostics. Moreover, there is emerging research strength within Wales in non-invasive imaging and biomarkers, with ongoing development of prognostic models through machine learning. WCB is helping to develop a

Trusted Research Environment (TRE) within Wales (see Objective 4 below) and is collaborating with AI-focused industry partners to aid the integration of different types of imaging data alongside clinical information on patients with the aim of informing treatment decisions in the future.

CReSt Theme 4:
Cancer Clinical Trials

WCB has a strong history of supporting collection of trials samples which are ultimately required to improve predictive biomarkers to establish who gains benefit from specific treatments, drivers of resistance or the identification of preventative interventions. WCB provides a mechanism for samples collected under a clinical trial protocol to be made widely available at the end of the trial to maximise use. Trials can request WCB to adopt samples under the WCB Human Tissue Authority licence to take ongoing responsibility for future use (in line with original consent parameters). Since 2020, WCB has adopted samples from 8 clinical trials which has promoted interest in accessing these samples from research groups not allied to the trial. We aim to work directly with the Cardiff Centre for Trials Research (CTR), and other trials units around the UK, to ensure that these valuable resources continue to be maximised and through coordination with WCRC, to engage with researchers to access this material.

CReSt Theme 5:
Palliative and supportive oncology

Access to samples with associated co-morbidity and related clinical data through the WCB clinical database has potential to support important research into several cancer related symptoms such as anorexia, sarcopenia etc. A range of linked anonymised clinical data including treatment history and co-morbidities is available for archived samples held by the bank from the past 17 years, through the Wales clinical portal. Alongside genomics and image analysis data, this represents an untapped opportunity for palliative and supportive oncology and population health research which merits further exploration.

CReSt Theme 6:
Population health-based cancer prevention, early diagnosis, primary care & health services research

As part of its initiative to broaden the scope of its biological resource, WCB has recently obtained ethical approval to collect pre-invasive cancer material from patients attending routine diagnostics clinics. This provides the potential for researchers to access pre-cancerous material for the development of early diagnostics and opens up possibilities for future population-based research using tissues derived from NHS diagnostics clinics. We will seek new collaborations in this area through WCRC and by advertising these new collections on our website and on-line networks.

Seven new Objectives for 2023-2028. WCB will address the following ***new Objectives*** to help meet its Strategic Aims that align with CReSt. These Objectives encompass a range of new cross-cutting and interrelated areas of collaborative research-related activity that WCB will be focusing on developing and expanding over the next 5 years. These specific objectives ***are in addition to***, and ***complement*** the existing core activities of the Biobank which are aimed at supplying the national and international cancer research communities with state-of-art biosamples and related data.

Thus, in addition to the 7 key Objectives below, WCB is committed to delivering and improving on its routine collection of biosamples to maintain the bioarchive, curation of trials samples and the provision of biosamples, expertise and data to the research community across the UK and internationally.

Objective 1

International and national biobanking leadership

WCB has an outstanding national and international reputation as a research biobank. We will continue to lead on international biobanking policy through senior representation on international biobanking bodies. We will also play leading roles in UK and EU initiatives to support biobanking networks. This will increase visibility of the resource internationally and widen the opportunities for sample access requests. WCB's willingness to be involved in a leading role in national efforts to harmonise and standardise biobanking processes will continue with a focus on streamlining access procedures across a core of interested biobank partners. An increased profile and the credibility gained from national and international collaborations will impact cancer research in Wales, potentially attracting new researchers to the Welsh research community and an uplift in sample requests.

Objective 2

Supporting new cancer research infrastructure

The Cardiff Cancer Research Hub. WCB will actively support through engagement and strategic leadership the development of the proposed tripartite NHS/Academic Cardiff Cancer Research Hub (involving UHW Trust, Velindre Oncology Centre and Cardiff University) which aims to provide a translational pipeline between laboratory and clinic within Cardiff. Supporting new cancer research infrastructure was one of the eight key recommendations in the CReSt document. Given the existing strong links with the NHS, WCB is naturally placed to provide infrastructure support for this research hub in the form of collection and methodology consultation, sample and data delivery. There is a translational and scientific need to better understand the impact of treatment on a cancer in vivo. This requires infrastructure support for research specific biopsies in patients which we could facilitate. Through our overarching ethics approval and using our expertise in sample acquisition and processing, we are uniquely placed to become embedded as a critical element in the strategic development and delivery of this new infrastructure.

ARCH – Swansea. A Regional Collaboration for Health established in 2015 is a complementary tripartite NHS/Academic infrastructure based in Swansea / South Wales that aims to deliver transformational change to NHS and pathology services in the region. Although more established than CCRH, there remains the potential for WCB to impact on research related sample collection and data delivery

The Cardiff Edge – Coryton. As part of the Genomics Partnership Wales initiative described in Objective 1, the creation of a 'Genomic Centre for Wales' based at the Cardiff Edge Life Sciences park in north Cardiff is due for completion in 2023. This development offers to make Wales a great place for NHS, academia and industry to work in genomics, and where the requirement for samples from WCB is likely to significantly increase. WCB will foster its existing collaborative links with stakeholders intending to relocate to this new site and to help promote a research and innovation agenda for the new Genomics Centre.

Cardiff Cancer Theme. Cardiff University is currently undergoing a review of its cancer research activity with the intention of delivering a new Cardiff Cancer Theme in 2023 which aligns to CReSt and focusses on its existing research strengths in cancer research. As a Cardiff University academic research infrastructure, WCB will play a prominent role in delivering on this University Theme, thus strengthening University engagement with WCB activity.

Objective 3

Early Engagement Program

This is a key principle of WCB future activity aimed primarily to increase critical research mass within Wales but also to impact on UK and EU based cancer research. We will engage with researchers early in the development of new ideas and major programs of work both to strengthen and direct new research funding applications. This approach will aid in the design of pre-clinical studies to maximise the use of patient material and will strengthen grant applications as funders seek robust quality-controlled sample delivery pipelines to support research. WCB research staff will be included in project budgets, helping to sustain the WCB workforce through external research income. WCB's original Multi-disciplinary Research Group (MDRG) program, now coordinated by WCRC, will be an important route of early engagement with Wales-based researchers to help promote research activity and critical mass within Wales. WCB will be represented at all MDRG meetings to ensure line of sight for new collaborations. A new program of follow-up with researchers who have previously engaged with WCB will be initiated to ensure continuity with follow-on projects.

Objective 4

The Cancer Trusted Research Environment (cTRE)

WCB currently plays a leading role in the development of a Cancer Research TRE (Trusted Research Environment) for multi-parametric cancer data. This has involved ongoing engagement with key infrastructure partners SAIL, WGP, WCRC, ECMC, CTR – WCP[7] and cross-talk with NHS partners (AWMGS) and data infrastructure networks (NDR). Our role has been to lead on exemplar research projects involving the WCB sample archive and linked clinical database to propose retrospective clinical trials of new diagnostic/prognostic technologies to aid treatment decisions in cancer clinics. This has previously culminated in new research and industry-linked funding for development of new diagnostics platforms including development of data infrastructure. We will continue to drive these research targets to their conclusion with new funding applications to UKRI and charitable bodies while also playing a prominent and pro-active role in the collaborative 'TRE' working group with the overall objective of supporting a research TRE platform (Cancer Research Data Hub) to benefit all cancer researchers and multiple research projects in Wales.

[7] Secure Anonymised Information Linkage Databank (Swansea); Wales Gene Park; Wales Cancer Research Centre; Experimental Cancer Medicine Centre (Cardiff); Clinical Trials Research – Wales Cancer Partnership

Objective 5

Training and development

WCB recruits early career technicians and graduate staff with basic research, health care and clinical backgrounds. Working off recent successes in biobanking training and engagement in post-graduate training programs (MSc, Interdisciplinary Doctoral Training Hub, Future Leaders in Cancer Research programs) we will continue to promote training and accreditation of our staff providing them with the research skills necessary for their own career development. In this way we will be supporting the skill-sets of our biomedical research workforce in Wales, promoting inward and outward recruitment across Wales. We will introduce additional biobanking and clinical pathology training opportunities for post-graduates and early career scientists outside of WCB and ensure our volunteers receive relevant training either through the volunteer consenting programme or as biobank advocates.

Objective 6

Patient involvement

Patient biosample donations continue to be at the heart of WCB's activity which identifies a strong connection between patient and cancer research in Wales. We also have an active lay liaison team which works internally within the governance structures of the biobank. Notwithstanding, we wish to investigate the potential for cancer patients (and cancer survivors) to become more actively engaged in WCB activities, providing a more tangible link between patient and their donated samples. We have initiated patient surveys and with the help of our lay liaison group will investigate the potential to tap into a valuable resource of voluntary engagement, including consenting and awareness. We will also engage in a survey to scope the possibility of recruiting patients to cohort studies for future population health-based research.

Objective 7

Supporting research and innovation activities across the NHS Wales Precision Medicine initiatives.

Precision medicine in Wales aims to achieve integrated diagnostics and advanced targeted therapeutics. Through a clear national vision, NHS services will be transformed to create sustainable, high quality, future-facing care pathways that have space for increased research, innovation and strategic partnerships. A focus on cancer is a key part of achieving this vision, and where WCB will act as a key enabler for many aspects including research and innovation. Thus, WCB will work with stakeholders across the following exemplar precision medicine initiatives and will engage with others across Wales where applicable to increase researcher access to clinical materials and to promote strategic partnerships.

- **The National Pathology Programme** led by the NHS Wales Health Collaborative is looking at the way that new technologies can be used to change the way that cellular pathology services are delivered. Digital pathology offers a national solution for cellular pathology in Wales and provides new opportunities for translational research into diseases such as cancer through the use of state-of-art technological advances including AI-based diagnostics. Wales Cancer Biobank will work with the NHS digital pathology programme to make images and associated tissues widely available to the research community enabling tumours not only to be accurately pin-pointed for study but also to be made available for more complex analyses consistent with the CReSt priority themes described above (for example, analysis of the tumour microenvironment).

- **Genomics Partnership Wales** is committed to 5000 extensive genomic testing profiles of patients with newly diagnosed cancer annually ensuring improved diagnosis in order to improve cancer outcomes. Linkage of genomics with biosamples provides a rich resource for future research and innovation which WCB is ideally placed to facilitate.

- **The Advanced Therapies Wales** programme involves adoption of ATMPs and Research, Development & Innovation across Advanced Therapeutics (eg. CAR-T services and gene therapy trial facilitation in Wales). Alongside service development and clinical trials, pre-clinical cancer research in Wales is advancing on all advanced therapy fronts, and access to patient tissue resources via WCB will be critical in many of these developments.