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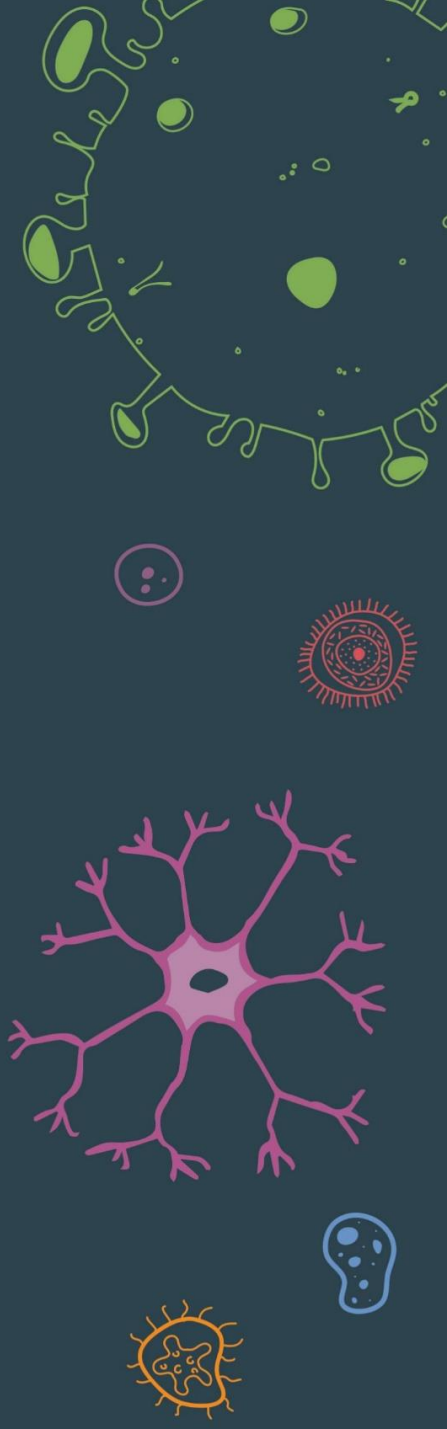
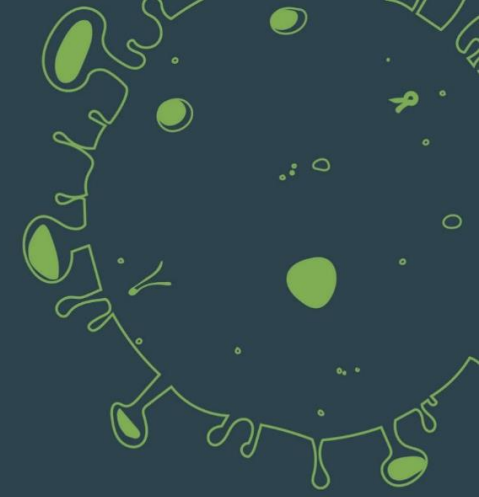


Cardiff University Biobank

Annual Report February 2022 to August 2023

Contents





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> The CUB vision is to provide high quality biosamples to research organisations

Introduction

This report encompasses CUB's activity between February 2022 to August 2023. In previous years CUB's annual report has encompassed 12 months worth of activity. This year the period has been extended to run to August 2023. This has been actioned to change when CUB's annual report is released each year from March to the Autumn.

CUB's activity has been growing since last year as a number of new collections were adopted into the biobank. These include samples from donors with Leukaemia and COVID-19. CUB has also established another collection which has ongoing recruitment. This is an expansion of the Cystic Fibrosis Collection as CUB now recruits both child and adult donors to the collection. This is an exciting opportunity to follow donors over the course of their disease lifetime.

Aims and Vision

The CUB vision is to provide high quality biosamples to research organisations throughout the UK, Europe and the rest of the world.

The CUB mission is to consistently meet customer expectations whilst strictly adhering to human tissue, data protection and biobanking standards and legislation. Our strategic direction is to successfully integrate the existing biobanks at Cardiff University into the CUB facility. We aim to maintain our certification and commitment to ISO 9001:2015 whilst expanding on current sample collections and creating new collections in areas not currently covered by the biobanks presently situated within Cardiff University.

CUB Academic Lead Report

I have always felt that the start of a new academic year brings renewed hope, optimism and excitement. New funding opportunities are being advertised, researchers are starting new projects, whilst other projects are reaching their culmination. In relation to this, don't forget that CUB is here to help you at all stages of the research 'life cycle' from providing funder approved quotations for access to key biosamples that will help de-risk a grant application, to the timely provision of biosamples for an on-going project, through to being a repository for biosamples that are no longer required but which can then be utilised by the wider research community.

Looking back, it's been 18 months since the last CUB report, but the time has just flown by! Having welcomed a couple of new staff members (Ed and Hoi) the biobank is now operating at full capacity again. Dare I say it, but CUB is also now operating more efficiently! This is, in part, due to improvements in our audit process driven by CUB's Quality Manager (Kieran). The audit schedule has now been streamlined and enhanced, reducing repetition and improving efficacy, whilst not reducing our high standards of governance and compliance. This was a key factor in CUB's ISO 9001:2015 re-certification in March 2023.

I mentioned in the last report about work around enhancement of CUB's digital interface and the way in which we connect with researchers and how they can connect with us. Well the good news is that CUB's new website and sample search platform are now up and running. The sample search now enables researchers to see, in real time, the collections/biosamples that CUB holds to help them decide whether we can support them in their project needs. Once samples have been identified they can be added to a 'basket' and checked out. This will generate a list of samples that can be provided to CUB alongside an application to access those samples. Please give it a try and feel free to provide us with feedback so we can continue to refine this interface.

Finally, a quick mention of the project support that CUB provides. Whilst the primary aim of most biobanks (including CUB) is to provide biosamples directly for research projects, CUB is also involved in the processing of samples to support ongoing research. To this end, we have been involved in a number of commercial projects recently with the aim of enhancing biosamples preservation and hence their applicability for research. Reports on these will follow in due course.

As always, if you have any feedback for CUB then please drop us a line as we are always looking to develop what we do to best service the needs of the research community.

Professor Phil Stephens
CUB Academic Lead

> **"CUB is here to help you at all stages of the research 'life cycle'"**

CUB Audit Improvements

Over the past year, CUB has made several changes to its audit schedule and process. Over time, the schedule had become congested with many audit areas subject to duplication. The changes made by CUB have sought to improve time efficiency and the effectiveness of the process whilst maintaining HTA compliance and conformance to ISO standards. As a result, several audit types have been removed, the frequency of some has been adjusted and two new audit types have been introduced.

The two new audit types now performed in CUB are In-Process Checks and Process Audits. In-Process checks aim to provide more assurance of sample and data quality. This means that any issues are identified and corrected at the time they are performed rather than later and will improve the live sample and data quality within CUB.

The second new audit type is Process Audits which provide an overview of a specific CUB process and all its requirements including but not limited to documentation, equipment and staff training. This method of audit not only ensures that all aspects of a process conform to the requirements but that all aspects of the process are suitable and work together effectively. As many requirements are checked during this audit type CUB has been able to remove a significant number of document specific and vertical audits.

Audit and Non-conformance

Audit

CUB currently conducts nine different types of audits. These are conducted for different regulatory reasons; to ensure compliance with the Human Tissue Act, to meet Health, Safety and Environmental standards and to meet ISO standards. The audits CUB conducts are as follows:

- **Health, Safety and Environmental Audits** are audits such as Work Place Inspections and Fire Safety Audits conducted as required to meet Health and Safety legislation
- **Traceability Audits** are audits that trace samples from database to sample location and from sample location to database and are required to meet the HT Act
- **ISO Audits** are audits against the new international biobanking standard 20387:2018 and ISO9001:2015
- **Vertical Audits** are audits that select a consent form and look at all records relating to it for completeness
- **Horizontal Audits** select a record type and look at a percentage of all that record type for completeness
- **HTA Audit** is an annual internal audit directly against the HTA standard
- **Data Audits** are six monthly audits that interrogate CUB's sample database for record completeness
- **Process Audits** are monthly audits to provide ongoing assurance of the technical processes within CUB
- **In–Process Checks** are performed contemporaneously to ensure ongoing quality of CUBs samples and data

Audit

CUB conducted 155 audits in total between February 2022 and August 2023. Figure 1 shows the number of audits conducted by type. The largest number of audits conducted were health and safety audits (26%). With the change in how CUB audits from a more proactive process driven approach the number of vertical and horizontal audits reduced upon last year (11% in the February-January period). CUB also introduced a process audit in the 2022-2023 period. Only one HTA audit was conducted as this is required annually.

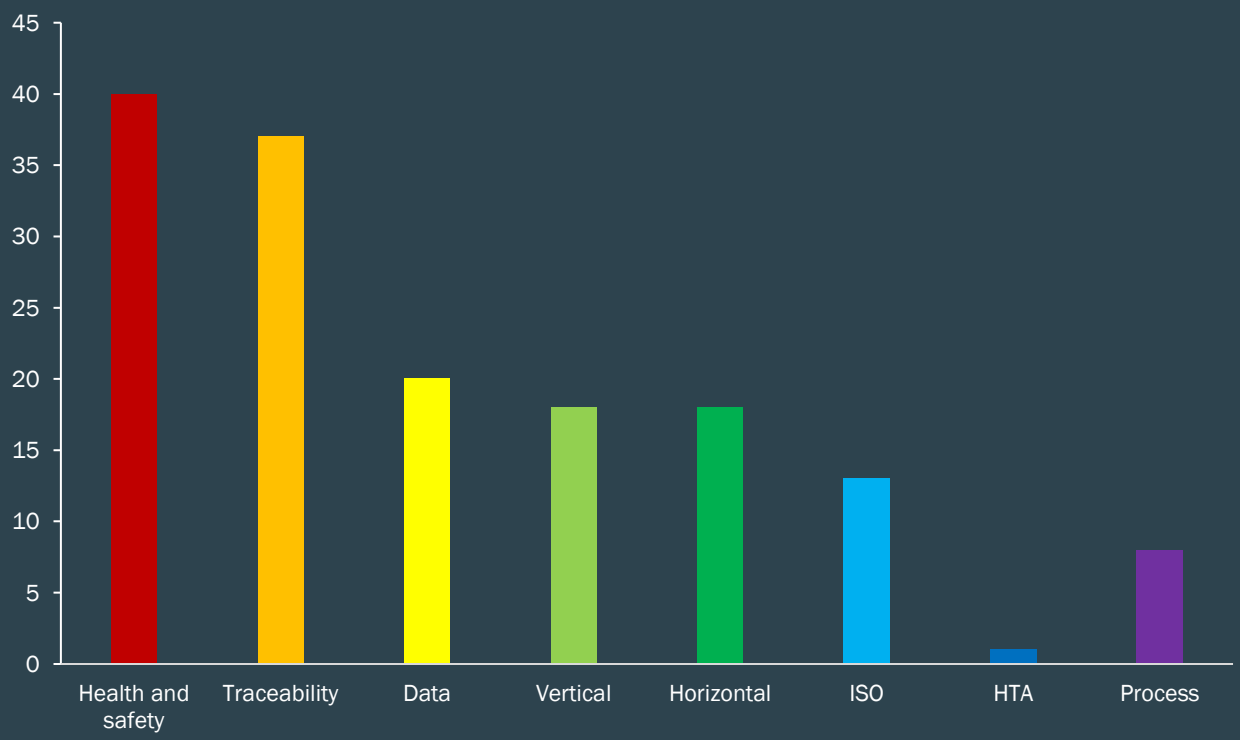

Figure 1: The Number of audits conducted by type between February 2022 and August 2023

Non-conformance

The majority of non-conformances raised within CUB were found during an audit (52%) (see Figure 2). 93% of these non-conformances were closed by their target date. The other non-conformances were found in an *ad-hoc* manner (41%) with 88% of these closed by their target date. Over the February 2022 to January 2023 time frame roughly the same number of non-conformances were found compared to 2021-2022 (54 vs 57) . Across all audit types, 92% of non-conformances were minor with 6% major (see Figure 3). No non-conformances were categorised as critical.

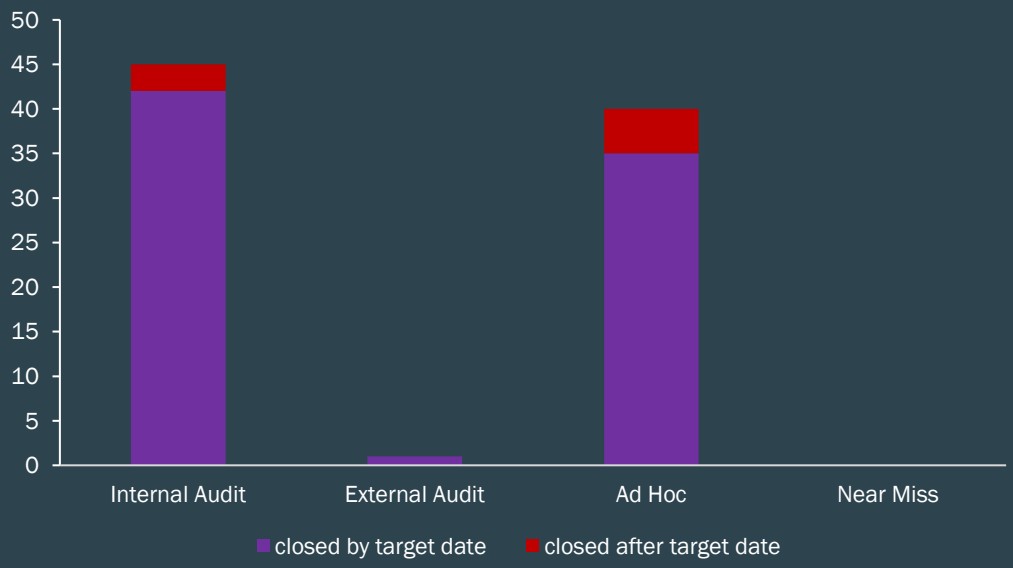

Figure 2: Number of Non-conformances raised by type

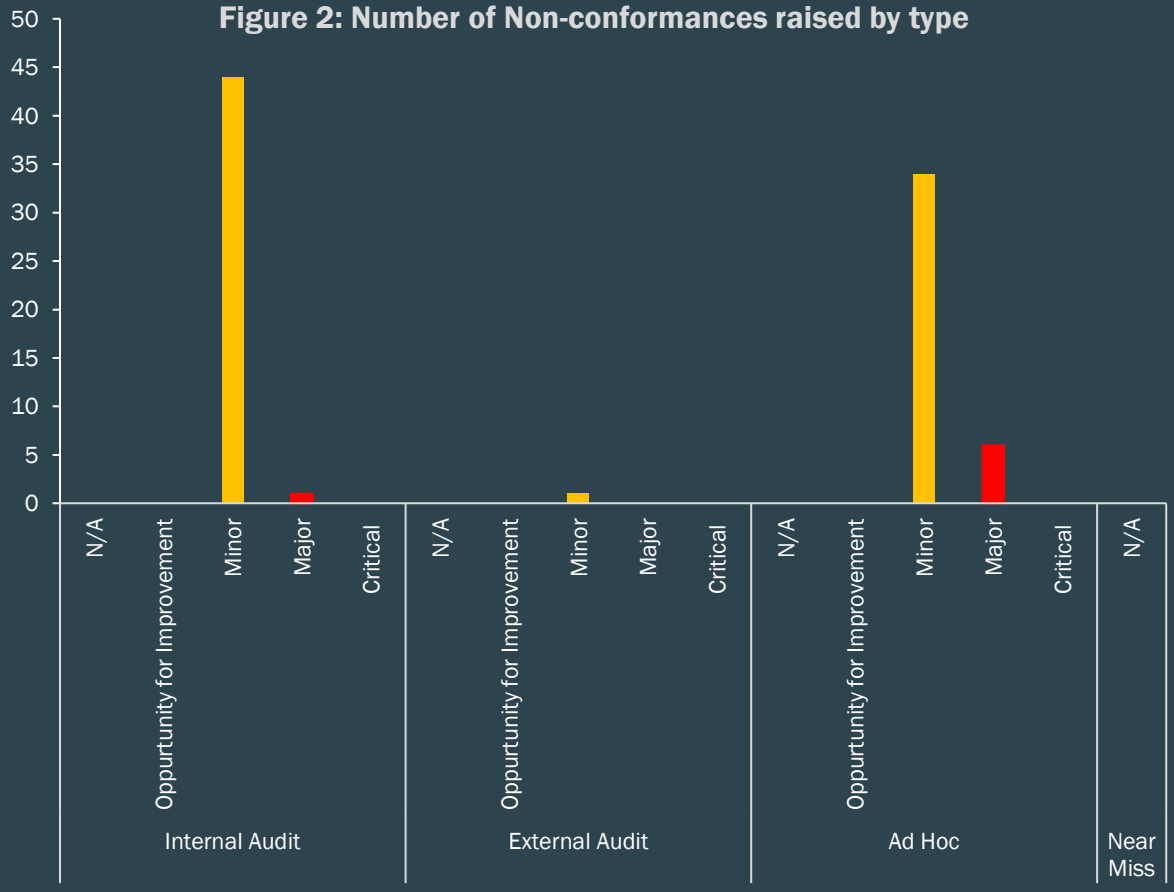

Figure 3: Number of Non-conformances raised by severity


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CUB Sample collections

The CUB has a number of different existing collections within the biobank, some of which are actively recruiting and some that are closed, existing studies. All samples are supplied anonymously to approved projects.

Healthy Volunteer Collection

This collection consists of samples collected from donors that are classified as healthy. These samples are collected within the biobank using CUB's dedicated phlebotomy suite. The CUB is ethically approved to collect blood, urine and saliva samples. After sample collection, donors are asked to complete a questionnaire about their health and lifestyle. Samples from the healthy volunteer collection can be released as fresh samples or from storage.

Elite Sports Person Collection

This collection consists of samples collected from donors that are classified as elite sports persons. Samples collected from these donors are blood and saliva. Samples from the elite sports person collection can only be provided from storage.

Cystic Fibrosis Collection

This collection consists of samples collected from donors that are diagnosed with cystic fibrosis. This collection has samples from both children and adults. Samples collected from these donors are blood and sputum. Samples from the cystic fibrosis collection can be released as fresh samples or from storage.

Anatomy

This collection is a collaboration between CUB and the Wales Centre for Anatomical Examination (WCAE). CUB collects samples from donations to the WCAE. These samples are all embalmed tissues. Samples from the anatomy collection can be collected bespokely if required or released from storage.

Acute Myeloid Leukaemia

This collection consists of samples from completed clinical trials from patients with acute myeloid leukaemia. Samples collected from these donors are primary cells (bone marrow mononuclear cells or peripheral blood mononuclear cells). Samples from the acute myeloid leukaemia collection can only be released from storage.

Neurofibromatosis-1

This collection consists of samples from patients with neurofibromatosis 1 (NF1). This collection is mainly frozen and formalin fixed paraffin embedded tissues. Samples from this collection can only be released from storage.

DUTY

This collection consists of samples from the completed DUTY clinical trial from child patients with suspected urinary tract infections. Samples collected from these donors are urine. Samples from this collection can only be provided from storage.

INDUCE

This collection consists of samples from the completed INDUCE clinical trial from patients with diabetic foot ulcers. Samples collected from these donors are wound swabs, swab washes and serum. Samples from this collection can only be provided from storage.

PACE

This collection consists of samples from the completed PACE clinical trial from patients with chronic obstructive pulmonary disease. Samples collected from these donors are sputum and swab washes. Samples from this collection can only be provided from storage.

Hidradenitis Suppurativa

This collection consists of samples collected from donors that are diagnosed with Hidradenitis Suppurativa. Samples collected from these donors are tissue and blood. Samples from this collection can be provided from storage only.

Dental

This collection consists of samples collected from donors that are having teeth extracted in the Dental Hospital on the Heath Park site. Samples collected from these donors are teeth. Samples from this collection can be provided from storage only currently but CUB will be looking to also provide fresh samples in the future.

Chronic myelomonocytic Leukaemia

This collection consists of samples from the completed clinical trial Monocle from patients with chronic myelomonocytic leukaemia. Samples collected from these donors are primary cells (bone marrow mononuclear cells or peripheral blood mononuclear cells) and serum. Samples from this collection can only be released from storage.

COVID-19

This collection consists of samples collected from donors that are diagnosed with COVID-19. Samples collected from these donors are saliva. Samples from this collection can be provided from storage only.


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Donor Recruitment

CUB has been recruiting to a number of its collections during 2022, including the Cystic Fibrosis collections (both adult and paediatric), the Hidradenitis Suppurativa collection and the Healthy Volunteer collection.

Recruitment this year has been predominantly to the Adult Cystic Fibrosis collection (48%) (Figure 4) with the next largest recruitment to the Healthy Volunteer collection (28%) and a smaller number to the Hidradenitis Suppurativa (13%) and Paediatric Adult Cystic Fibrosis (11%) collections.

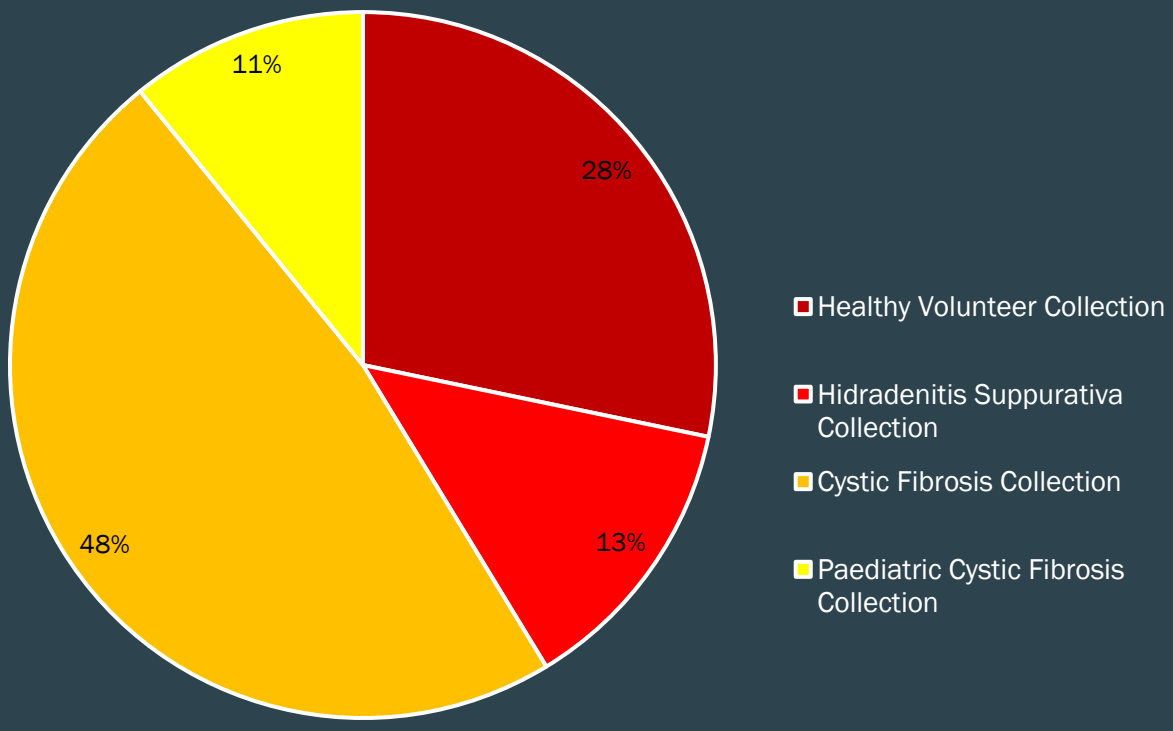


Figure 4: Percentage of donors recruited split by collection

Age and sex splits show that most participants were in the 20-29 age bracket (41%) with more female donors being recruited (64% vs 36%) (Figures 5&6). The recruitment is fairly evenly split across the other age groups with donors being recruited in the 0-15 age group for the first time. That fact that most donors were recruited in the 20-39 age group is likely because CUB's recruitment has been predominantly from patients that have Cystic Fibrosis which effects younger people.

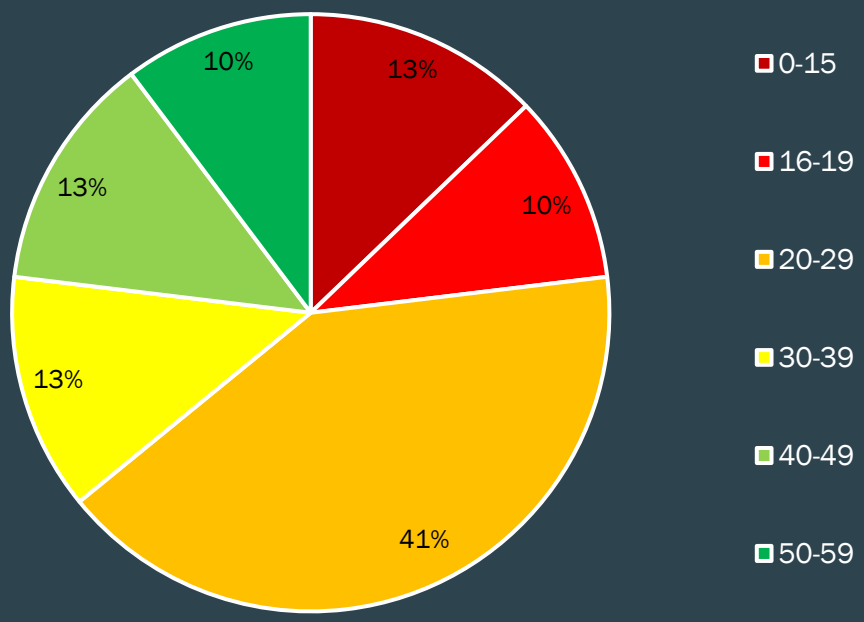


Figure 5: Percentage of donors recruited by age

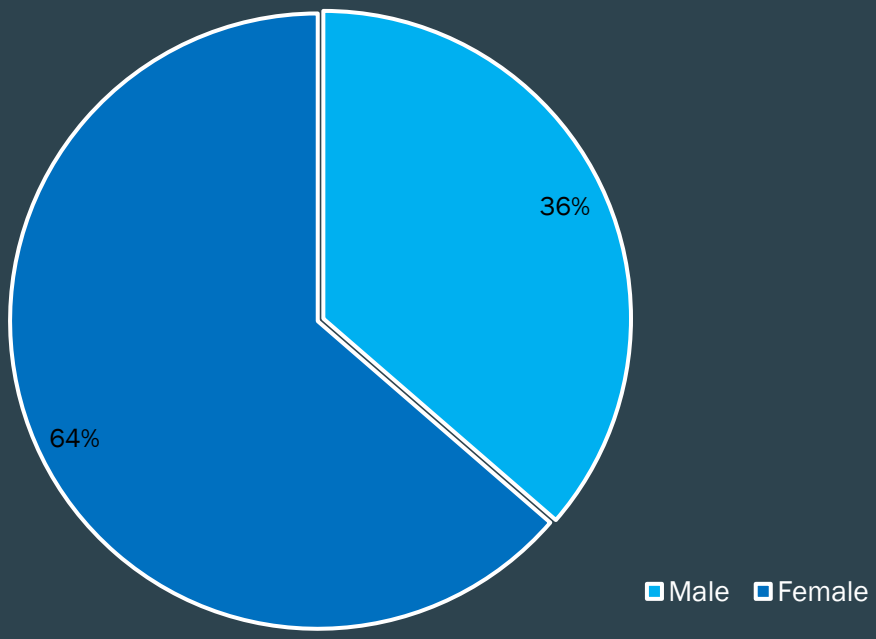


Figure 6: Percentage of donors recruited by sex

Total Sample Storage

CUB has samples stored as part of a number of collections. Figure 7 shows the aliquots currently stored in CUB as of August 2023 split by collection.

The largest number of aliquots stored are from the closed clinical trial DUTY (47% of all samples stored) with samples from the AML clinical trials second largest (14% of all samples stored). The largest collection of samples directly collected by CUB is for the Adult Cystic Fibrosis collection (8% of all samples stored) . The smallest number of aliquots for any sample collection is from the paediatric cystic fibrosis collection (0.03% of all samples stored) this is due to recruitment to this collection only just commencing.

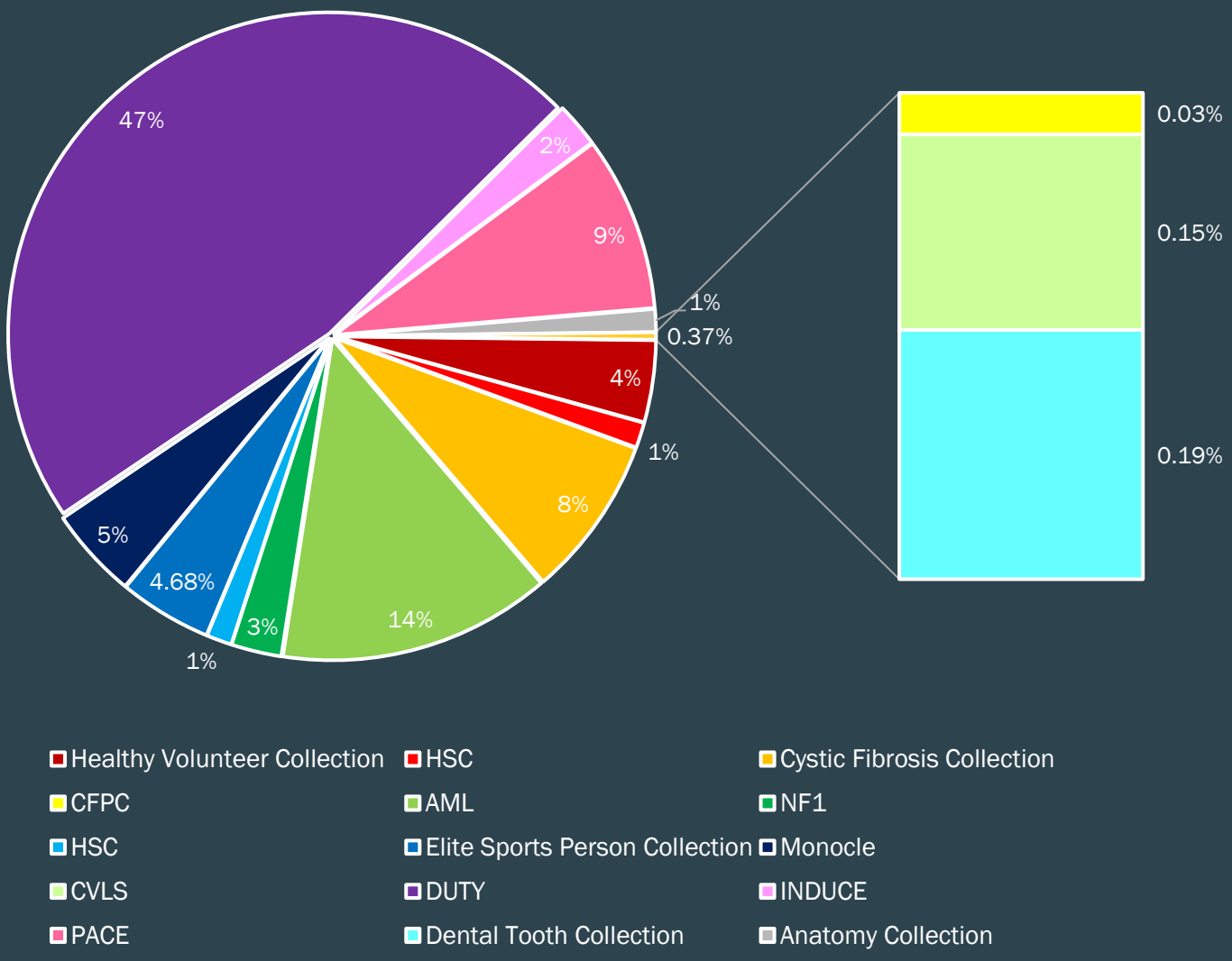


Figure 7: Percentage of aliquots stored by collection

Total Sample Storage

Figure 8 shows the aliquots currently stored in CUB as of August 2023 split by sample type.

The largest number of aliquots stored are of urine (48% of all samples stored) with primary cells the second largest (16% of all samples stored) and whole blood the next (9% of all samples stored). The smallest number of aliquots for any sample collection is cough swabs (0.02% of all samples stored).

> “48% of all samples stored are urine”

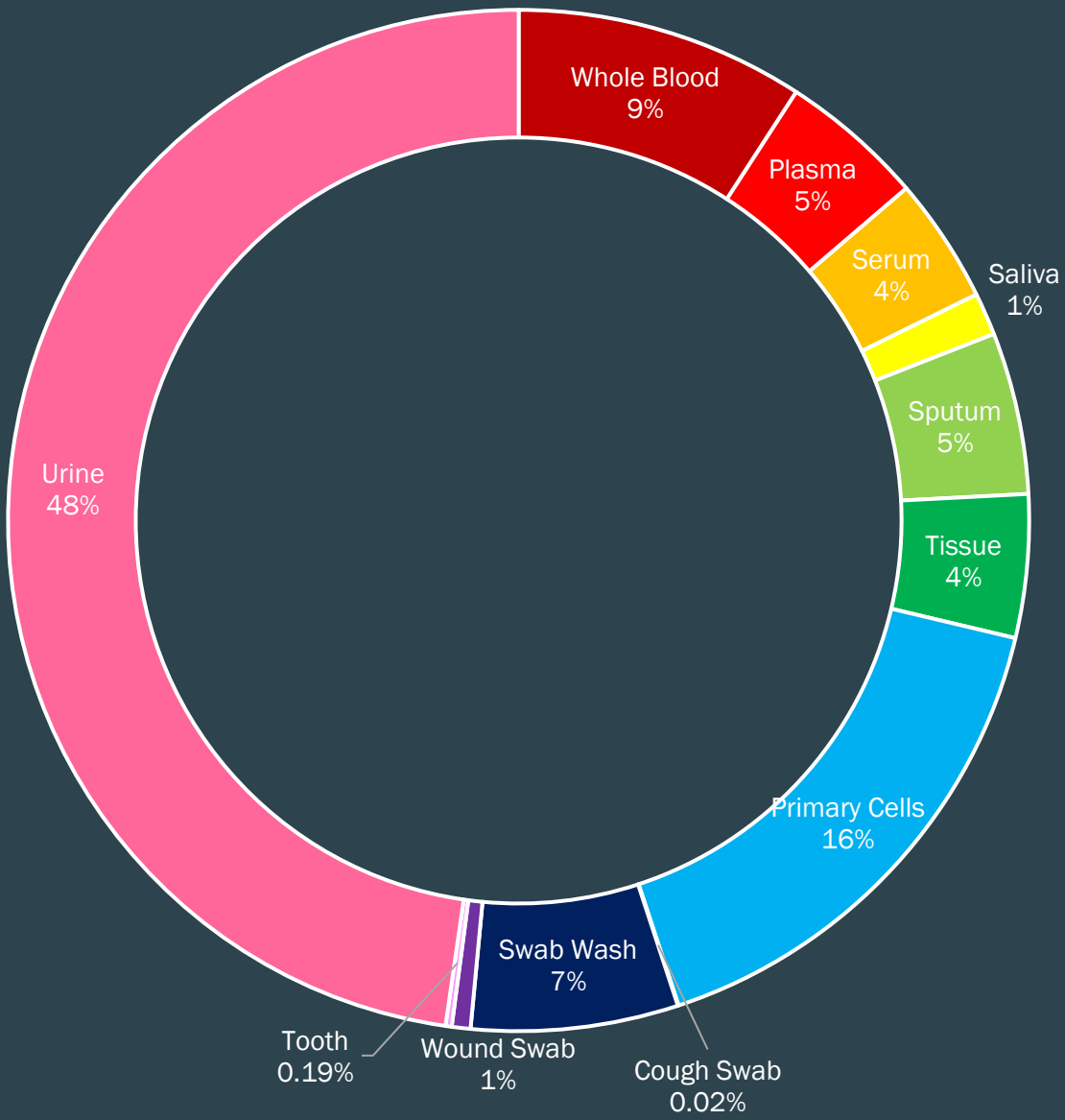


Figure 8: Percentage of aliquots stored by sample type

Sample Release

As show in Figure 9, most samples were release from the AML trials (36%) with the Hidradenitis Suppurativa collection the next most released (30%). The majority of samples released were tissue (40%), with primary cells being the next most common (36%) (see Figure 10). The tissue released was both fresh and from storage, with the primary cells were released from storage.

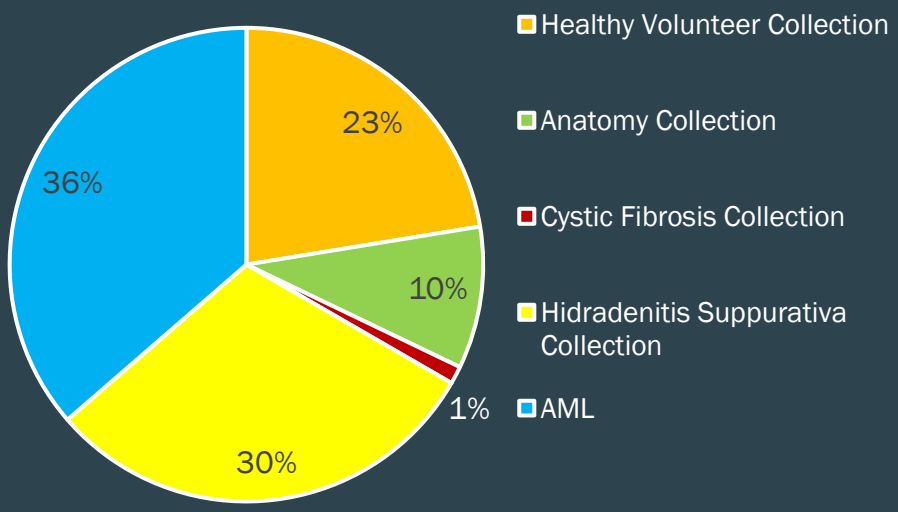
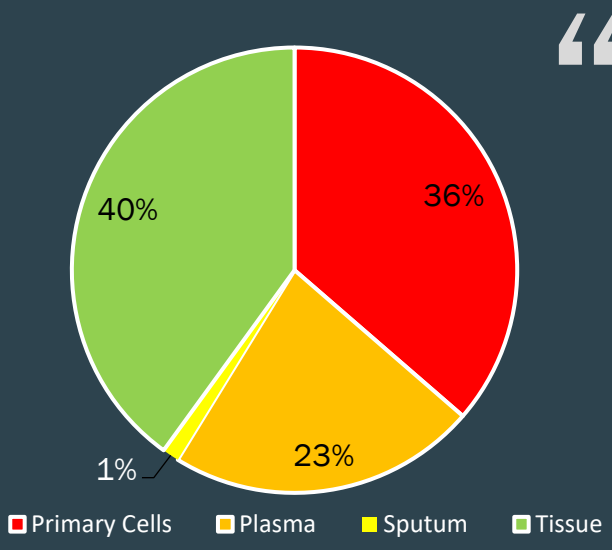


Figure 9: Percentage of samples released by collection



"40% of samples released have been tissue"

Figure 10: Percentage of samples shipped by type

Services

CUB has a number of services that it is able to offer to researchers:

Storage

CUB is able to provide storage for sample collections both small and large and short and long term. CUB will provide secure and monitored storage and ensure that any legal requirements are met. We currently have a number of both short and long term storage requests being handled by CUB.

Project Support

CUB can provide support for research projects. CUB is able to consent participants under a researcher's own ethics and then collect samples (blood, urine and saliva). CUB staff are consent and phlebotomy trained and the facility has a dedicated phlebotomy room. CUB can also process and store samples for the project. CUB is currently supporting a project in this way.

Lab Services

CUB is able to provide some basic processing of samples within the facility including the aliquoting and production of blood derivatives (serum, plasma) and the production of paraffin embedded tissue blocks. CUB has supported a project with the production of blocks for their research.

Quotations for Future Research

CUB has been providing quotations for our services and for grant applications throughout 2022/23 (see Figure 11). CUB provided 45 quotes in 2022/23. In the February 2022- January 2023 CUB provided 29 quotes which was comparable to the number of quotes provided in the same period last year. In the February 2022-August 2023 period the value of the quotes provided by CUB amounted to just under £174,000.

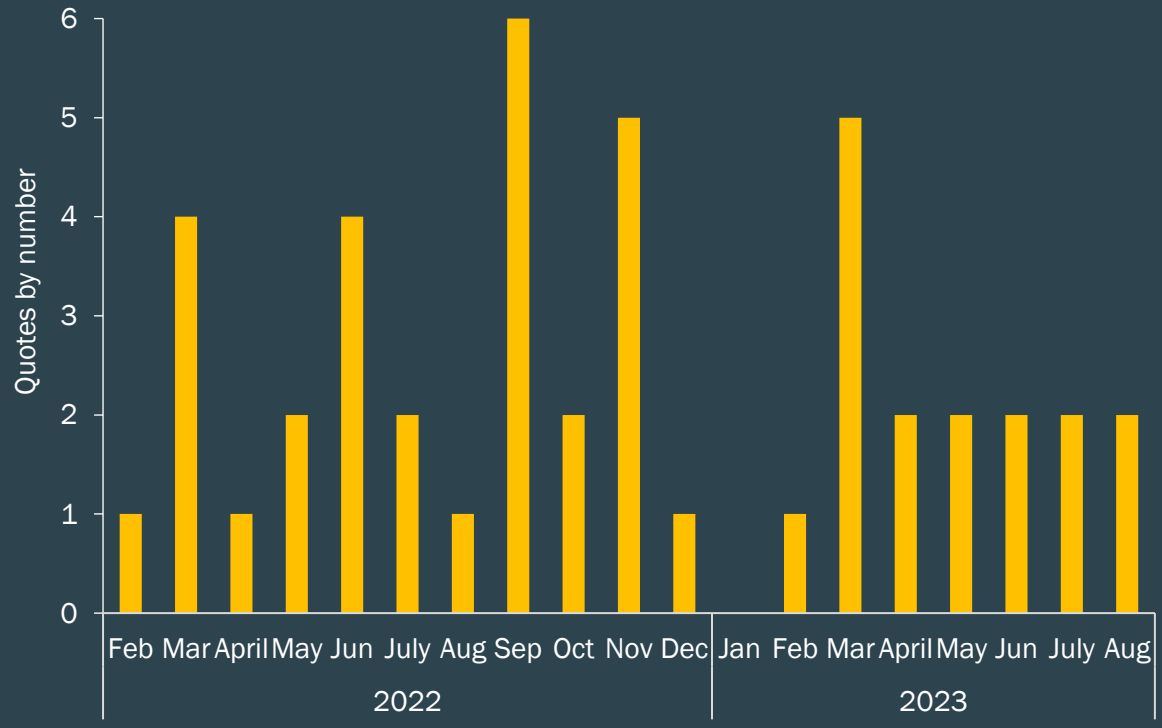


Figure 11: Quotations issued by CUB between February 2022 and August 2023

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