



Biobank
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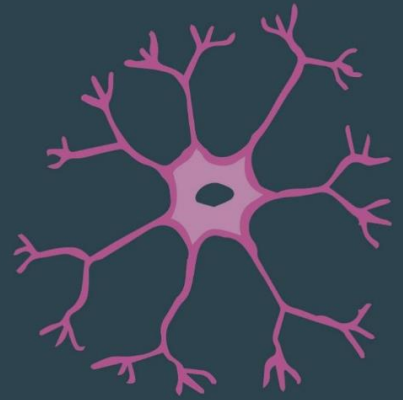
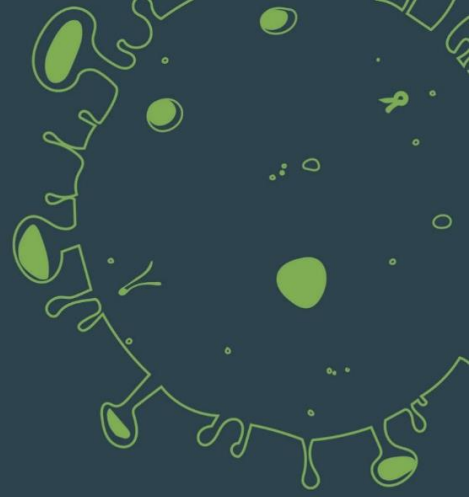


Cardiff University Biobank

Annual Report
February 2020
to January
2021

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Halter

Salvum

Salvum

ULTIMATE TEMPERATURE PROTECTION

8.8°C

“ The CUB vision is to provide high quality biosamples to research organisations ”

Introduction

This report encompasses CUB's activity between February 2020 and January 2021. CUB had to pivot to change its focus in 2020 due to the COVID-19 pandemic.

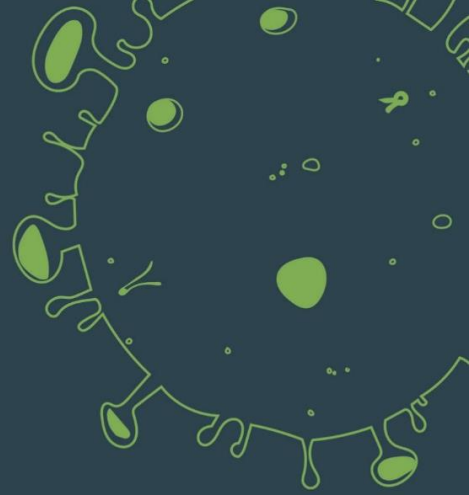
The biobank facility was closed between March 2020 and October 2020 with all sample collections ceasing and with staff working from home. Whilst working from home the CUB team remotely managed already stored samples and continued to undertake other work.

This has meant that CUB's activity in terms of donor recruitment, sample acquisition and sample release has been minimal this year. However, CUB has pivoted to support COVID-19 related work being undertaken in the University and beyond.

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

Well, as Dinah Washington once sang “What a Difference a Day Makes” or in CUB’s case “What a Difference a Year Makes”! In our last annual report, I reflected on the on-going integration of some of the existing tissue banks at Cardiff University, starting new tissue collections and undertaking discussions with Health and Care Research Wales around all-Wales biobanking.

However, in March 2020 the developing global pandemic disrupted life as we know it and with that, how CUB could operate. Yet, with great change comes great opportunity and so I’d like to reflect on a couple of positives that have percolated through the devastating global effects that have touched all our lives.

First, is the amazing capacity of our health system, but more specifically the way in which research and development within the NHS has really risen to the challenge. The rapid way in which clinical trials have been developed and approved and the collegiate way in which we have worked across Cardiff University with Cardiff & Vale University Health Board and with Public Health Wales (in which CUB has played its part) has been highly gratifying. I hope this will provide a blueprint for closer/more effective working in the future enabling CUB to support a wider range of researchers in their scientific endeavours to improve the health of our population.

Secondly, is the way in which the work landscape has changed as many of us have had to transition to the world of ‘virtual’ meetings. What this has meant though is wider inclusivity at meetings engendering a more holistic input and more rounded thinking around some of the challenges we have had to address. Whilst many of us yearn for the day when we can physically return to the workplace, I do hope the lessons of online working are not lost and can be adapted to deliver structures (e.g. national electronic consenting) which best support research and patient involvement in our activities within CUB.

Finally, a personal thank you to the CUB staff that have kept our facility going during the various lockdowns. Whilst we do have the benefit of remote monitoring of the facility, CUB staff have still had to physically attend to ensure all the samples that we are custodians of are still being stored optimally ready to be released for studies when the situation allows. Also well done on delivering a successful ISO 9001 re-accreditation.

With the COVID situation changing rapidly, I’m a little unsure about what to predict for CUB for the next year. Needless to say, I am confident we can continue to support our existing tissue banks and grow our new collections offering researchers in new disease areas the opportunity to undertake groundbreaking research for the future health and well-being of us all. Stay safe.



Professor Phil Stephens
CUB Academic Lead

“.. with great change
comes great opportunity”



COVID-19

Cardiff University COVID-19 Screening Service

In response to the COVID-19 pandemic Cardiff University set up a COVID-19 screening service to screen its staff and students. CUB supported the implementation of the service providing guidance on the set up of the service. This was particularly around the setup of collections sites and collection of samples. CUB continues to provide assistance by sitting on the services operational group. CUB is also providing support to assist the service in gaining ISO accreditation.

COVID Related Project

CUB was able to support a project early in the pandemic that was developing tests for COVID-19. The study required serum samples that were COVID-19 negative and CUB had samples that were in storage that had been collected before the pandemic and were therefore definitely COVID-19 negative.

Governance

Ethics submissions

This year CUB has submitted three amendments to its ethics. All were given favourable opinions.

These amendments are as follows:

May 2020

This amendment was to allow consent to be taken over the telephone for patient and healthy volunteer donors

September 2020

This amendment was to allow the setup of a new collection, a COVID-19 collection which included being able to seek consent from users of the University's COVID-19 screening service to allow any leftover samples to be used for research purposes

December 2020

This amendment was to allow the use of e-consent to seek consent from the users of the University's screening service



Audit and Non-conformance

Audit

CUB 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:

- **Work Place Inspections** are inspections of all work areas as required to meet Health and safety legislation
- **Fire Safety** audits are inspections of all fire safety equipment as required to meet Health and safety legislation
- **Traceability** audits are monthly audits that trace samples from database to sample location and from sample location to database and are required to meet the HT Act
- **ISO 20387:2018** are audits against the new international biobanking standard
- **Vertical** audits are monthly 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
- **ISO 9001:2015** audits are risk based and directly against the ISO 9001:2015 standard
- **HTA** audit is an annual internal audit directly against the HTA standard
- **Health, Safety and Environmental** audit is an annual internal audit to ensure CUB is working in line with the ISO4001 and OHSAS18001 standards



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Audit

CUB conducted 51 audits in total between February 2020 and Jan 2021. Figure 1 shows the number of audits conducted by type. The largest number of audits conducted were Workplace inspections (22%). The number of audits conducted were greatly reduced this year versus 2019 (143 in 2019). This was mostly due to the pandemic as most audits required access to the CUB facility which has not always been possible throughout 2020. CUB also stopped conducting audits to the OECD (Organisation for Economic Co-operation and Development) Guidelines for Human Biobanks and Genetic Research Databases standard in 2019 as this was superseded by the Biobanking ISO standard. Only 1 of each of the HTA and Health and Safety audits were conducted as these are performed annually only.

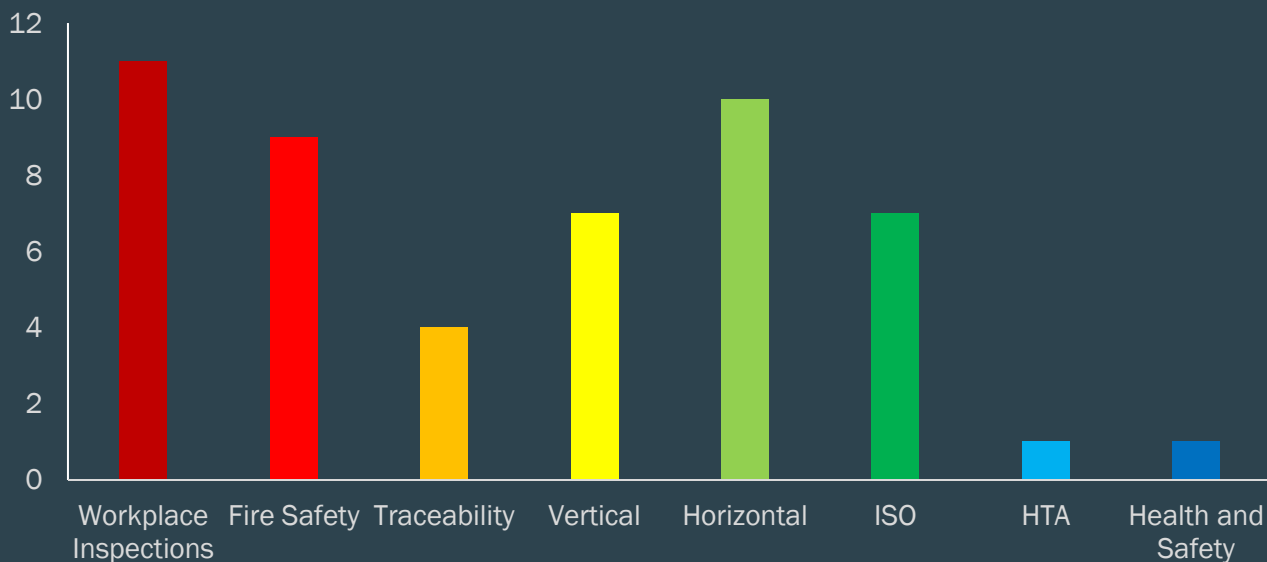


Figure 1. The Number of audits conducted by type between February 2020 and January 2021

Non-conformance

The majority of non-conformances raised within CUB were found in an *ad hoc* manner (67%) (see Figure 2). 77% of these non-conformances were closed by their target date. The next highest number of non-conformances were found via internal audit (33%) with 100% of these closed by their target date. Far more non-conformances were found outside audits in 2020. This is due to CUB recording a lot of non-conformances related to being unable to conduct scheduled tasks (audits, cleaning, equipment maintenance) due to the pandemic. Across all audit types 98% of non-conformances were minor with 2% opportunity for improvement (see Figure 3). No non-conformances were categorised as major or critical.

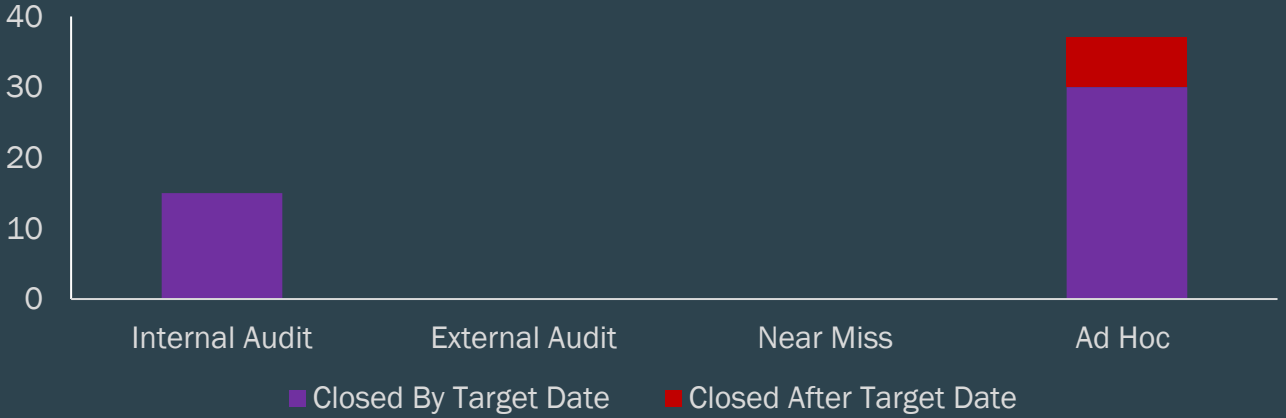


Figure 2 Number of Non-conformances raised by type

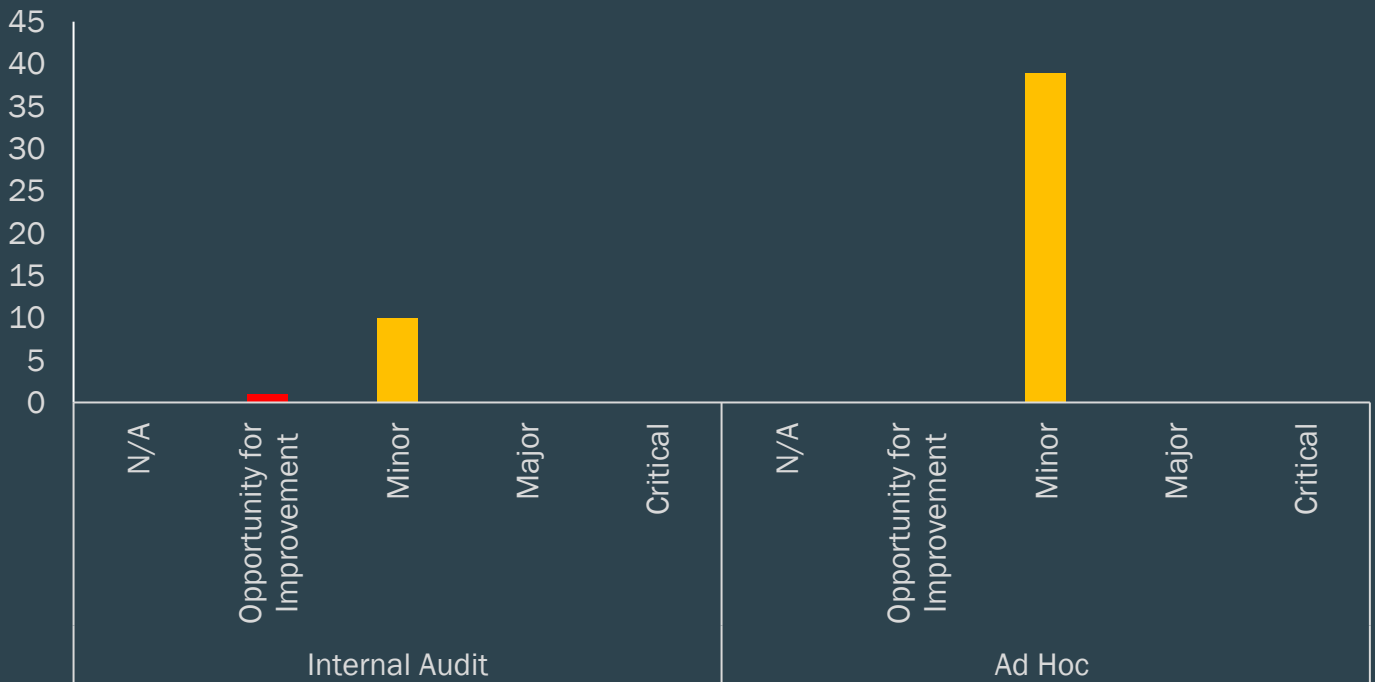


Figure 3 Number of Non-conformances raised by severity



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 with only blood and saliva currently being collected. 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 and 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. Samples collected from these donors are blood and sputum. Samples from the cystic fibrosis collection can be released as fresh samples and from storage.





Anatomy

This collection is a collaboration between CUB and the WCAE. CUB collects samples from donations to the WCAE. These samples are all embalmed tissues. Samples from the anatomy collection can be collected bespoke 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 and 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.

CUB also has some new collections that became available in 2020:

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 is 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 is 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.



STATEBOURNE

biosystem 100

www.statebourne.com

Donor Recruitment

CUB has been recruiting to a number of its collections in 2020, the Cystic Fibrosis Collection and Hidradenitis Suppurativa Collection. Recruitment to the Healthy Volunteer Collection had to cease in 2020 due to the pandemic but CUB is hopeful to begin recruitment again in 2021. Figure 4 depicts the number of donors recruited by month. Recruitment has been predominantly to the Cystic Fibrosis collection (85%) (Figure 5) with a small number of participants recruited to the Hidradenitis Suppurativa collection (15%). Recruitment over the last year has been erratic due to the pandemic. No donors were recruited between the middle of March and the middle of October due to the biobank facility being closed during this period. Recruitment in February 2020 and November and December 2021 was steady. Recruitment has dropped off in Jan 2021 due to another lockdown being in place which is reducing the number of patients attending clinics.

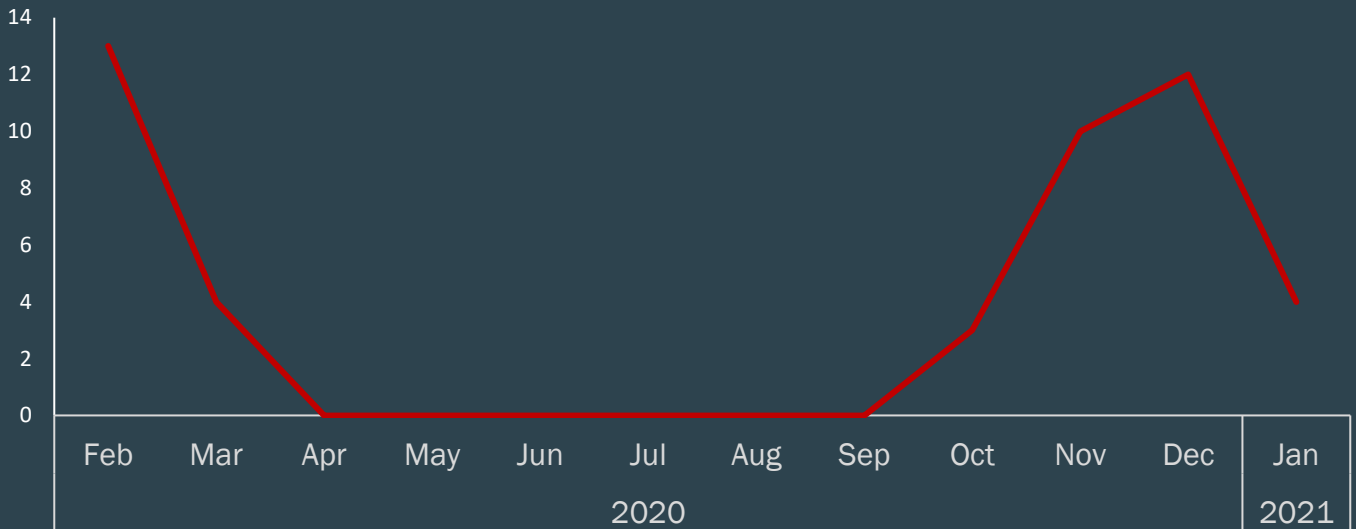
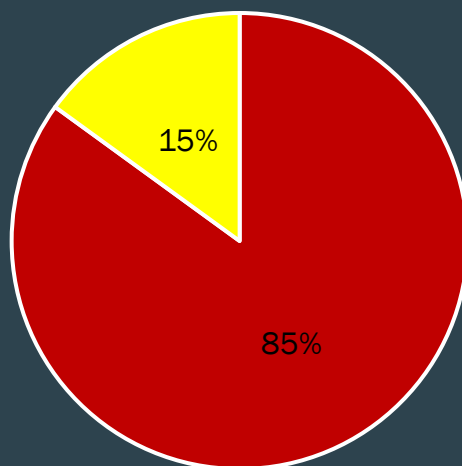


Figure 4 Number of donors recruited by month between February 2020 and January 2021



■ Cystic Fibrosis Collection ■ Hidradenitis Suppurativa Collection

Figure 5 Percentage of donors recruited split by collection

Age and gender splits show that most participants were in the 20-29 age bracket (41%) but gender was equally split (Figure 6 and 7). The next largest age group is 30-39 (30%) and then 40-49 (17%) with recruitment fairly evenly split across the other age groups (16-19 [4%], 50-59 [6%], 60+ [2%]). That fact that most donors are recruited in the 20-39 age group is likely because most of CUB's recruitment up until January 2021 has been from patients that have Cystic Fibrosis which effects younger people.

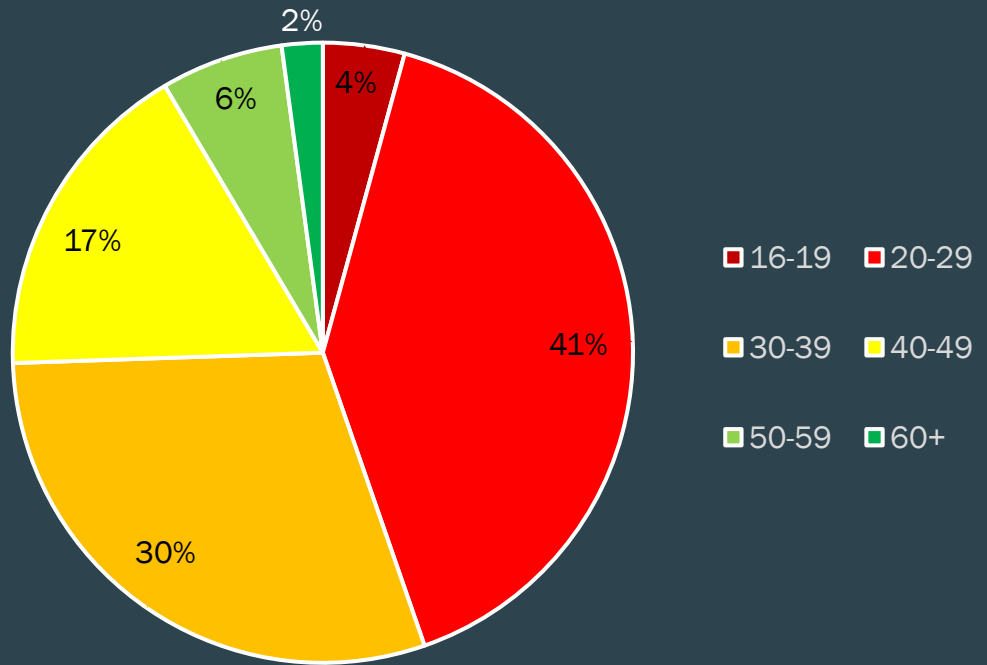


Figure 6 Percentage of donors recruited by age

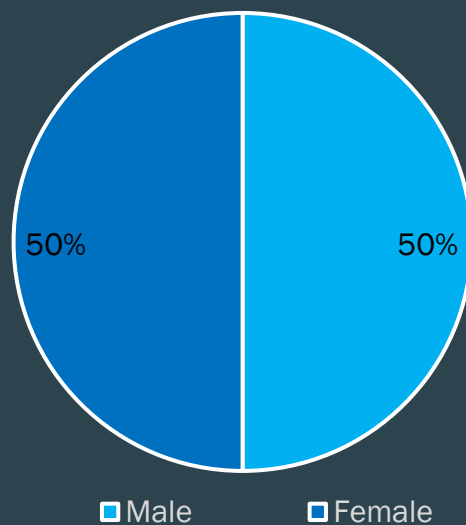


Figure 7 Percentage of donors recruited by gender

H36

WOLF
01759 301142

H37

WOLF
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H38

WOLF
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H39

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H40

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Sample Storage

CUB has samples stored from a number of collections currently. Figure 8 shows the aliquots currently stored in CUB as of Jan 2021 split by sample type and collection.

The largest number of aliquots stored are of urine (56% of all samples stored) with primary the second largest (14% of all samples stored) and swab wash the next (8% of all samples stored). The smallest number of aliquots for any sample collection is teeth (0.2% of all samples stored).

The large volume of urine stored is due to the movement of the DUTY clinical trial into CUB that consists of over 10,000 aliquots.

“56% of all samples stored are urine”

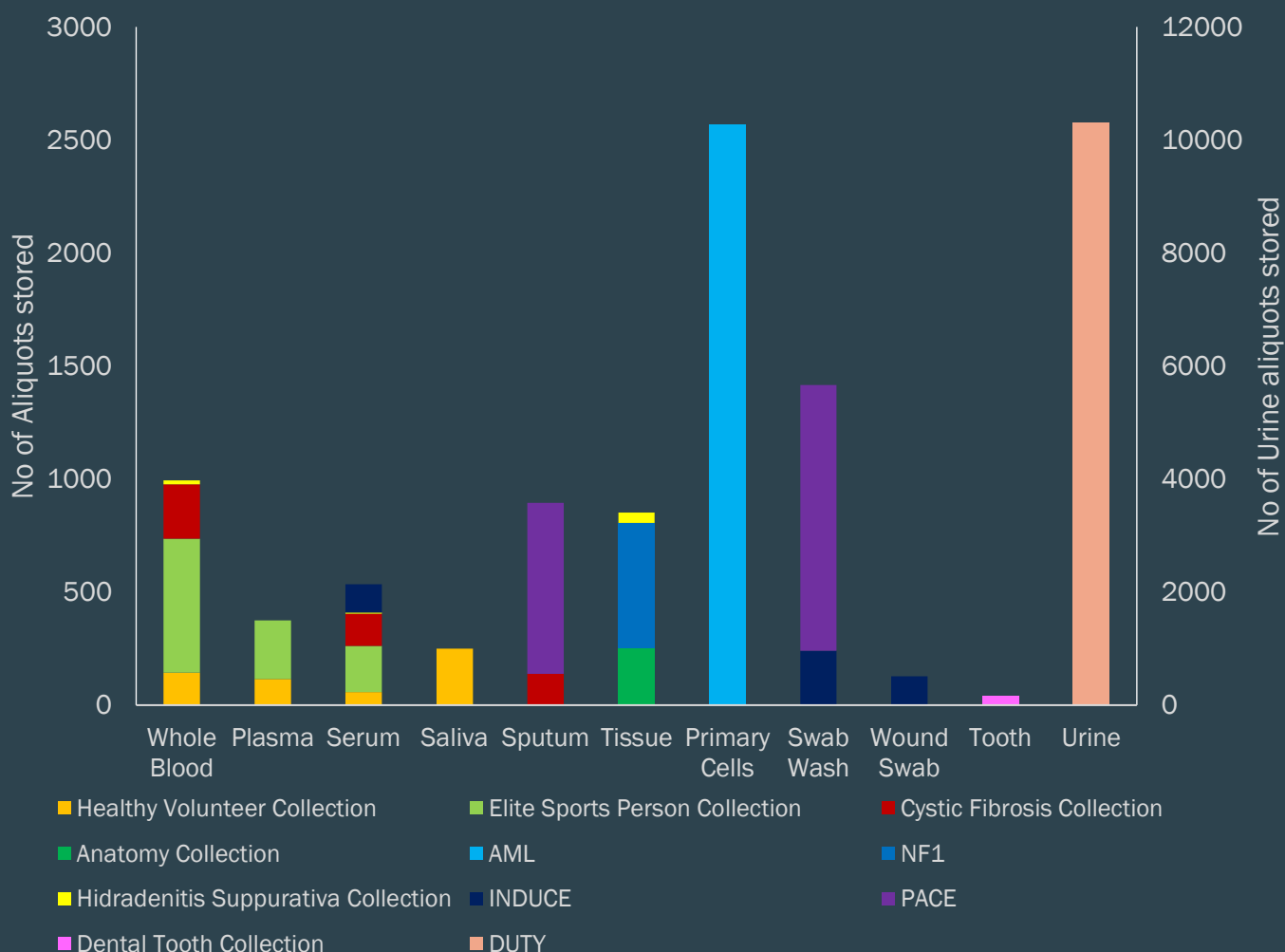


Figure 8 Number of aliquots stored by sample type and collection

Services

Due to access to samples being reduced in 2020 CUB focused more on the services that we were able to provide.

Storage

As detailed elsewhere CUB provided temporary storage for a very large number of samples. We also provided a number of quotes for projects also looking to utilise CUB storage. Undertaking the large storage request has been particularly helpful to CUB to show that we can support these kinds of requests with ease.

Project Support

CUB has had a number of requests to support research projects by taking consent on their behalf and collection of samples within the CUB facility. CUB has recently collected blood to support a research project and is planning to support a further project shortly. 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.

Lab Services

CUB is able to provide some basic processing of samples within the facility. This was only aliquoting and production of blood derivatives (serum, plasma) but this now includes the production of tissue blocks. CUB will shortly support a project with the production of blocks for their research.



Sample Application

Applications and supply of biosamples

In the last year CUB has received five applications to access fresh and stored samples. This low number of applications is likely due to the pandemic as 2 out of the 5 applications were received in January 2021 and numbers of applications have been increasing since the beginning of 2021. All applications received have been approved. The lay summaries for all applications can be seen in Appendix A.

“

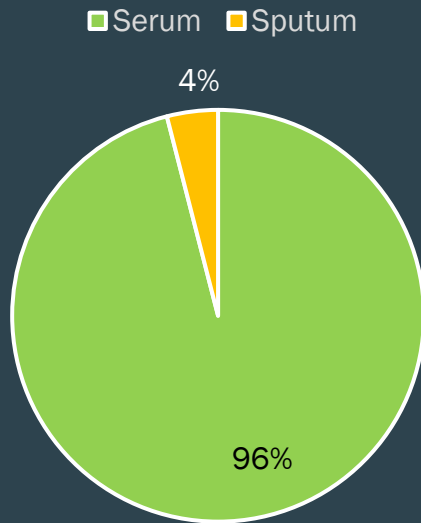
CUB is currently accepting applications to access samples from academic institutions and commercial companies in the UK and abroad

”



Sample Release

CUB has only released a small number of samples in 2020 due to the pandemic. These have all been from the Healthy Volunteer and the Cystic Fibrosis Collection. The majority of samples released have been serum (96%) (see Figure 9). The serum samples were release from storage and the sputum was released fresh. Figure 10 shows the release of samples split by month. Samples were released in two months only. This reflects samples being released to two projects in different months.



“ 96% of samples released have been serum ”

Figure 9 Percentage of samples shipped by type

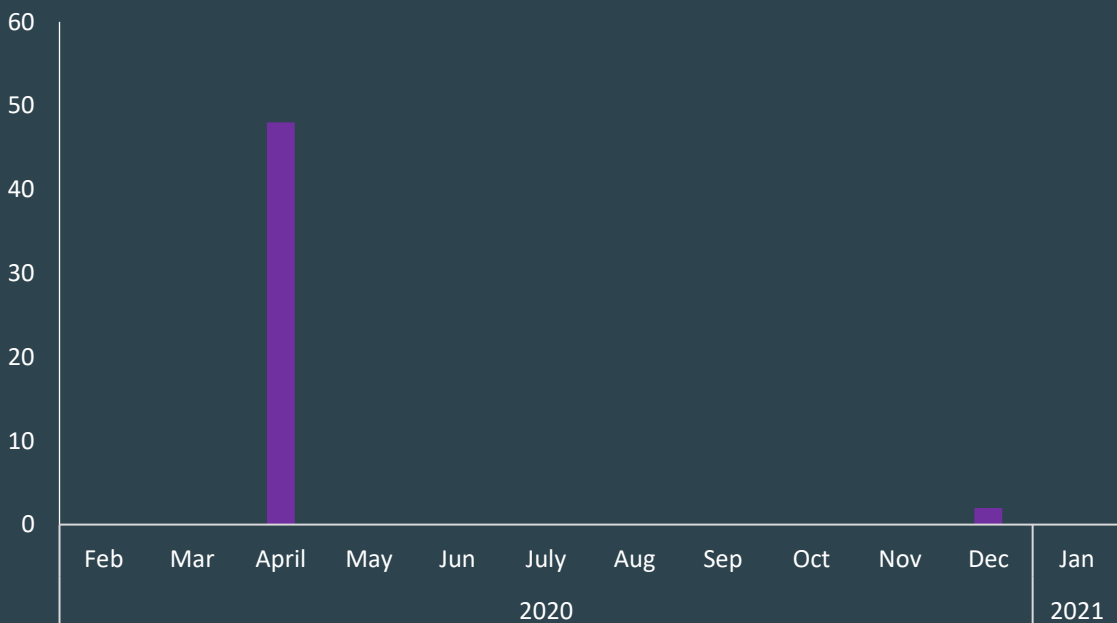


Figure 10 Number of samples shipped by month between February 2020 and January 2021

ISO 9001 and ISO 20387

With the ISO 20387 standard released in late 2018 the international biobanking community has responded positively with a number of biobanks already accredited.

Within the UK the United Kingdom Accreditation Service (UKAS) has taken responsibility for the accreditation of biobanks. Since UKAS do not have internal technical expertise of biobanking a Biobanks Accreditation Steering Group (BASG) was formed in early 2020 comprising of representation from human, animal, microbe and seed banks. The CUB Quality Manager, Christopher Thomas formed part of the steering group allowing CUB to both provide input to the process and gain best practice to improve our internal processes. The group have developed a deeper understanding and context around more complex parts of the standard which include quality control, validation, and verification.

In conjunction. UKAS launched a pilot project inviting biobanks to be part of the first formal accreditation group. Building on the work completed by the BASG, UKAS have appointed a number of technical experts to assist with the accreditation process. The CUB Quality Manager has again been appointed into this role, which again allows CUB to gain a much deeper understanding of the standard. This process is currently well underway but has experienced some delayed due to the impact of the COVID pandemic.

CUB continues to be certified to ISO 9001:2015 and have now completed two successful surveillance audits (the most recent in February 2021) with no non-conformances issued. Over the past 12 months CUB continue to work through an ISO 20387 internal audit schedule to ensure full alignment to the standard to enable accreditation at a later date.

“... CUB continues to be certified to ISO 9001:2015 and have now completed two successful surveillance audits with no non-conformances issued”





Quotations for Future Research

CUB has been providing quotations for our services for grant applications. CUB has been consistently providing quotes throughout 2020 (see Figure 11). CUB provided 19 quotes in 2020 compared to 30 quotes in the same period last year. This is likely to be due to research activity generally being reduced in 2020 and because CUB provided COVID-19 related services for free during the pandemic. However, the value of quotes provided in 2020 was great than that in 2019 reflecting CUB providing costs to support a smaller number of bigger projects in 2020 versus a greater number of smaller projects in 2019.

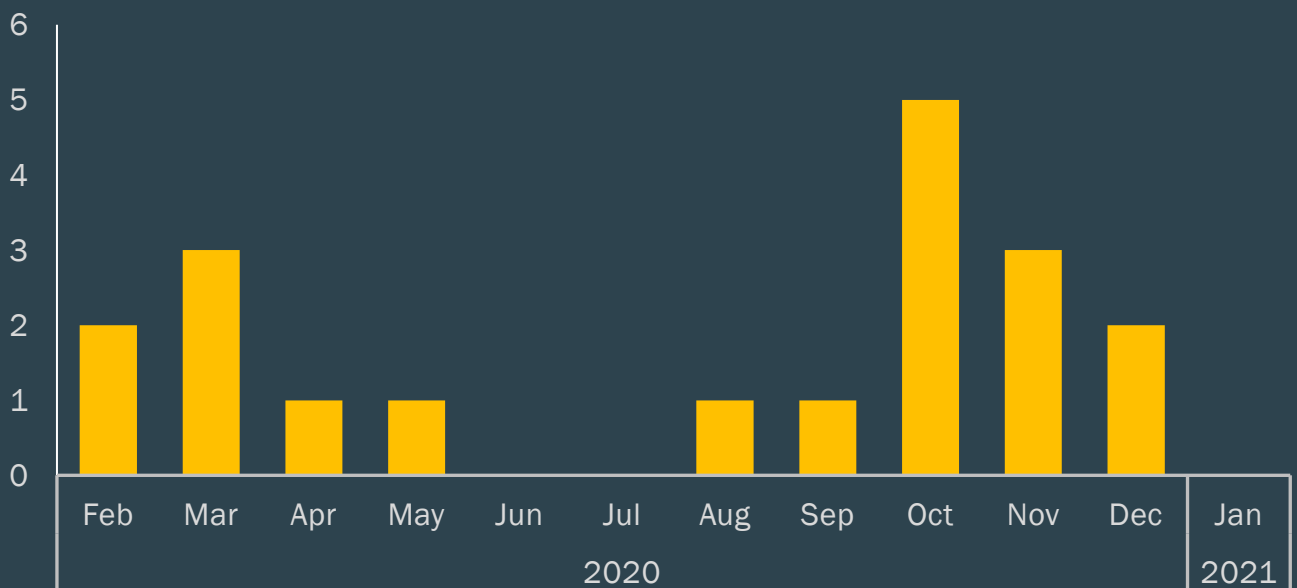
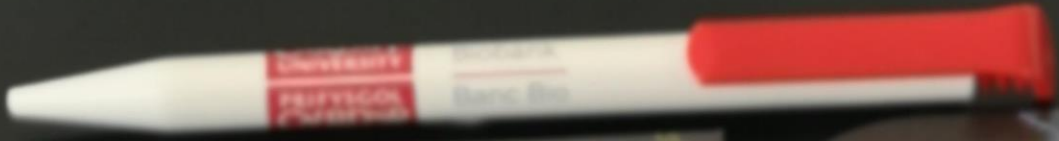


Figure 11 Quotations issued CUB between January 2020 and February 2021



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Do you like to make a difference by taking part in research?

Cardiff's brand new Biobank is looking for volunteers to donate samples of blood, urine and stool. These samples will be used by scientists to find better ways to diagnose, prevent and perhaps even find a cure to many common medical conditions and diseases.

These samples are vital for research and can help us make a difference.

If you are interested in taking part, please contact us near from you!

0775
f.ac.uk

 www.cardiff.ac.uk/biobank
 @CUBiobank



Communications

CUB has a dedicated website for the facility as well as a twitter account. CUB also regularly releases a newsletter for researchers. Figure 12 shows the average monthly users of the CUB website. The number of users of CUB's website has dropped throughout 2020. This drop off in interest may be due to CUB's website not having been updated in 3 years. CUB is looking to revamp our website in 2021 which will hopefully drive more people to the site.

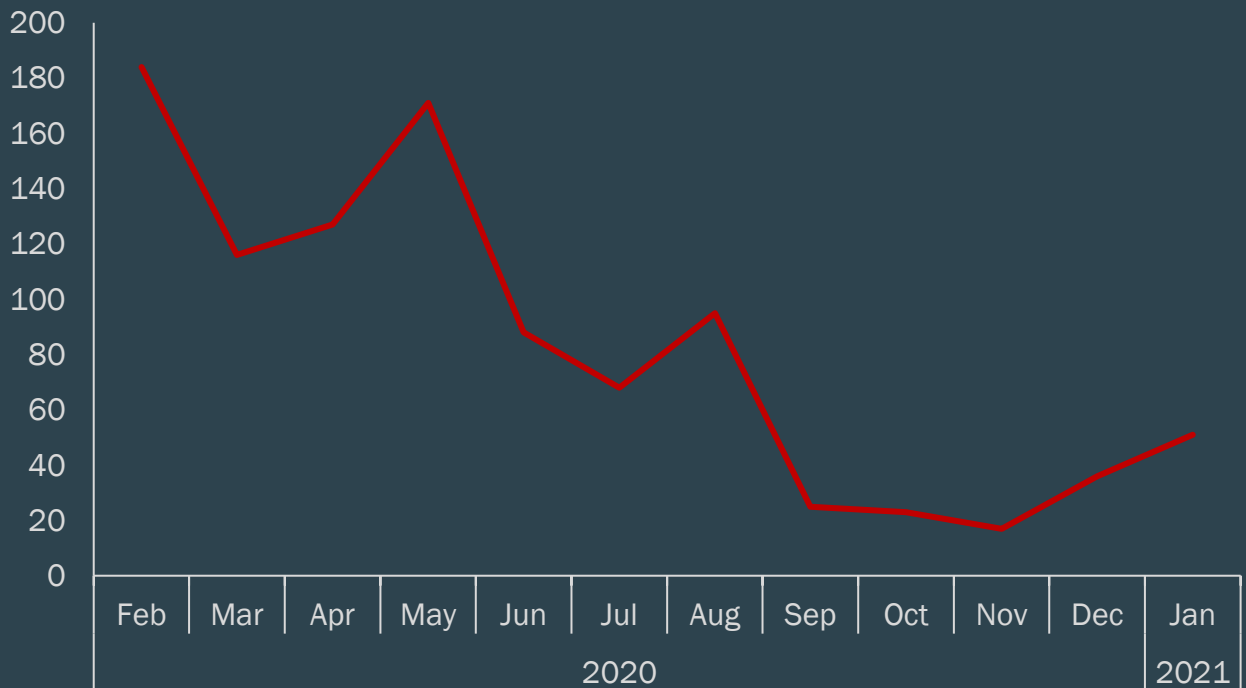
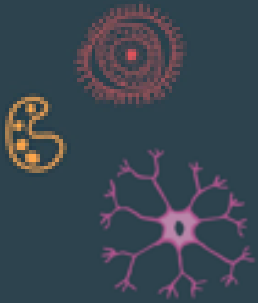


Figure 12 Average monthly users of the CUB website

Communications

CUB has increased its social media followers in 2020. CUB had 495 twitter followers in January 2020 which has risen to 604 by February 2021 (see Figure 13). CUB has on average 10.2 new twitter followers every month.

CU Biobank
@CUBiobank

604 Followers

Thank you to all the @CUBiobank followers and the international biobanking community for the support in helping us reach 600 followers! #biobanking #qualitymatters

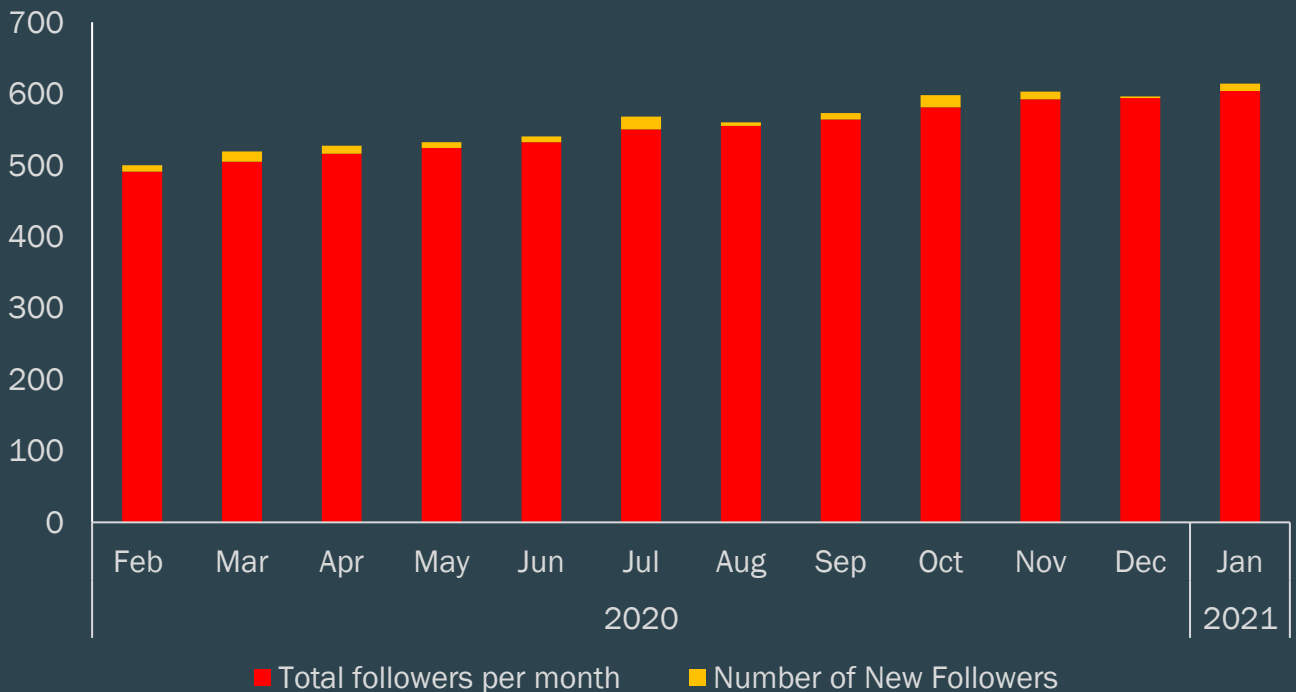


Figure 13 Number of total and new followers to CUB social media




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Appendix A

Lay summaries

Prof Stephen Jolles, Cardiff and Vale University Health Board

Rapid assay validation of bedside and laboratory platforms for serological diagnosis of recent or previous COVID-19 infection in the NHS Clinical Immunology Laboratory

The emergence of a highly infectious novel coronavirus (SARS-CoV-2) in December 2019 has given rise to the greatest challenge faced by our healthcare system in the last century. Part of the body's immune response to infection is to create specific antibodies. In March 2020, a collaborative effort between Cardiff University and the NHS was conceived to rapidly validate antibody-based testing for COVID-19. Serum shared from pre-pandemic healthy blood donors from the CU-Biobank provided important samples to act as negative controls. The healthy control serum allowed a rapid assessment of the rate of false positive results, and the accuracy of different tests. Recognising who has previously been exposed to the virus and recovered is important at an individual level, as a only a true positive result suggests they will have gained a degree of protection against severe disease if re-exposed. At a population level, this knowledge also helps inform on progress towards possible herd immunity on a larger scale ("sero-epidemiology").

Prof Alex Tonks, Cardiff University

Re-wiring the metabolism of cancer cells – therapeutically targeting glycolytic metabolism of blood cancers

Acute myeloid leukaemia (AML) patients (77% >60y) fail to survive 5 years from diagnosis. There remains an urgent need for alternative treatment strategies, which lies in the development of targeted agents that seek to exploit increased knowledge of mechanisms that drive this disease. We found a common abnormality in most AML patients (>60%), that is the over-production of reactive oxygen species (ROS). We have shown that AML cells use ROS to promote cell growth by over-producing a specific enzyme (PFKFB3) that can increase sugar (glucose) consumption. Previously, we showed that AML cells are dependent on this enzyme to thrive. Our next major goals are to establish for the first time the biological significance of the levels of this enzyme in AML patient samples and whether it plays an important role in mediating ROS effects in AML tumour cells from patients. Given that there is already a specific inhibitor of this enzyme tested in solid tumour clinical trials, we will use this agent to determine whether cells from AML patients are vulnerable to this treatment.



Dr Elaine Dunlop, Cardiff University

Investigating EV-associated RNA as a biomarker in Tuberous Sclerosis Complex

Biological changes in the blood which are different between people with a condition and those without are called biomarkers. Biomarkers have the potential to be able to help with diagnosis of diseases as well as monitoring how well people respond to medications. They are of interest clinically as they allow doctors to get information about a person's condition from a blood test, so avoiding the need for scans or other more invasive tests.

Tuberous Sclerosis Complex is a rare genetic condition, where patients develop cysts and tumours in many organs. No blood biomarker signature has been investigated for TSC, but it could help during diagnosis or to monitor how well patients respond to medication to help shrink their tumours. This project will compare blood samples from healthy controls and TSC patients to uncover differences and create a list of potential biomarkers. Promising candidates could then be investigated further in future, larger studies.

Dr Elaine Dunlop, Cardiff University

Characterising the role of extracellular vesicles in Tuberous Sclerosis Complex

Tuberous Sclerosis Complex (TSC) is a genetic disease where tumours grow in many vital organs, including the brain, lungs, kidneys, skin, and heart. Understanding why and how these tumours grow is important as it could allow the development of more treatment options for patients.

We know that tumour cells rely on the cells surrounding them to support tumour growth and survival. Some of this support is provided through small structures called extracellular vesicles. These extracellular vesicles contain protein which can instruct nearby cells to act in a certain way. The vesicles can act locally to the tumour but can also be circulated in the blood around the body. We are interested in learning more about these vesicles as their protein contents could tell us vital information about what TSC tumours require for growth and survival. This may reveal new ways to treat the tumour with medication. Additionally, they may be useful as markers of disease in blood tests.



