



### Report Cover Sheet

Report to:	Trust Board	
Date of the Meeting:	28 October 2020	
Agenda Item:	P1-162-20	
Title:	R&I Annual Report 2019/20	
Report prepared by:	Gillian Heap	
Executive Lead:	Sheena Khanduri	
Status of the Report:	Public	Private
	X	

Paper previously considered by:	R&I Senior Operational Meeting Integrated Governance Committee Quality Committee
Date & Decision:	1 <sup>2th</sup> October 2020/22 October 2020

Purpose of the Paper/Key Points for Discussion:	To review the performance of the R&I Directorate during 2019/20.
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Action Required:	Discuss	
	Approve	X
	For Information/Noting	

Next steps required	
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*The paper links to the following strategic priorities (please tick)*

Deliver <b>outstanding care locally</b>		Collaborative system <b>leadership</b> to <b>deliver better patient care</b>	
<b>Retain</b> and <b>develop outstanding staff</b>		Be <b>enterprising</b>	
<b>Invest</b> in <b>research &amp; innovation</b> to deliver <b>excellent patient care</b> in the future		Maintain <b>excellent</b> quality, operational and financial <b>performance</b>	

*The paper relates to the following Board Assurance Framework (BAF) Risks*

BAF Risk	Please Tick
1. If we do not optimise quality outcomes we will not be able to provide outstanding care	
2. If we do not prioritise the costs of the delivering the Transforming Cancer Care Programme we will not be able to maintain our long-term financial strength and make appropriate strategic investments.	
3. If we do not have the right infrastructure (estate, communication & engagement, information and technology) we will be unable to deliver care close to home.	
4. If we do not have the right innovative workforce solutions including education and development, we will not have the right skills, in the right place, at the right time to deliver the outstanding care.	
5. If we do not have an organisational culture that promotes positive staff engagement and excellent health and well-being we will not be able to retain and attract the right workforce.	
6. If we fail to implement and optimise digital technology we will not deliver optimal patient outcomes and operational effectiveness.	
7. If we fail to position the organisation as a credible research partner we will limit patient access to clinical trials and affect our reputation as a specialist centre delivering excellent patient care in the future.	
8. If we do not retain system-side leadership, for example, SRO for Cancer Alliance and influence the National Cancer Policy, we will not have the right influence on the strategic direction to deliver outstanding cancer services for the population of Cheshire & Merseyside.	
9. If we do not support and invest in entrepreneurial ideas and adapt to changes in national priorities and market conditions we will stifle innovative cancer services for the future.	
10. If we do not continually support, lead and prioritise improved quality, operational and financial performance, we will not provide safe, efficient and effective cancer services.	

Equality & Diversity Impact Assessment		
Are there concerns that the policy/service could have an adverse impact on:	YES	NO
Age		
Disability		
Gender		
Race		
Sexual Orientation		
Gender Reassignment		
Religion/Belief		
Pregnancy and Maternity		

If YES to one or more of the above please add further detail and identify if a full impact assessment is required.



**The Clatterbridge  
Cancer Centre**  
NHS Foundation Trust

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## **Annual Report 2019-2020**

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# **Research and Innovation Directorate**

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### **Prepared by:**

**Dr Gillian Heap, Director of Research & Innovation Operations**  
**Professor Nagesh Kalakonda, Clinical Director of Research & Innovation**  
**Dr Sheena Khanduri, Medical Director**

**R&I Senior Management Team - Fiona Keys, Dr Maria Maguire, Michelle Moffitt, Jane Tinsley,  
Emma Whitby**

### **Designed by:**

**Jess Moffitt, Research Project Manager**

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# Research & Innovation Annual Report 2019-20

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## 1. Introduction

The Research and Innovation (R&I) Directorate has had an exceptional year in 2019/20. This report details notable operational successes achieved during this time period.

It is a very exciting time for research at The Clatterbridge Cancer Centre (CCC), as a new and refreshed Research Strategy sets out an ambitious plan for the next five years.

### 1.1 Summary

The R&I Directorate is led by the Director of R&I Operations, Dr Gillian Heap and the Clinical Director for R&I, Professor Nagesh Kalakonda. The Executive Lead is the Medical Director, Dr Sheena Khanduri. The Director of R&I Operations is responsible for the operational oversight of all clinical and academic research taking place at the Trust and the Clinical Director for R&I is responsible for the strategic direction of research for the organisation. The R&I Directorate has ~65 staff and is made up of the Research Delivery Team, the Research Management and Governance Team and the Research Finance Team.

### 1.2 Developments

R&I at CCC has made significant progress this year:

- A new Director of R&I Operations was appointed in April 2019 and the role of the Clinical Director of R&I was also established. The R&I Directorate has since undergone a significant restructure of the management and governance arrangements to achieve our objectives.
  - Oversight committees within the Directorate have ensured engagement and participation of the wider Trust both in the clinical and allied service sectors.
  - The Research Finance Team was expanded and is now fully integrated into the R&I Directorate to provide robust fiscal support and oversight.
  - The research operational elements of the Haemato-oncology Team joined the R&I Directorate in 2020 enabling streamlined and proactive management of all research activities under one governance umbrella.
  - Eleven Site Reference Group (SRG) Research Leads were appointed to act as a conduit into the SRGs. See Appendix I for a list of SRG Research Leads.
- The CCC Research Strategy has undergone a refresh (pending Board approval) with an ambitious vision and plan for the next five years. It is hoped that the strategy will be underpinned by significant Trust investment which aims to position CCC as a nationally and globally recognised centre for cancer research. The new strategy, improved infrastructure, and robust governance will help embed research into the core activities of the Trust as we migrate to CCC-Liverpool and improve patient choice, experience and outcomes through access to state of the art treatments for cancer.

## 1.3 Notable achievements

R&I has overseen the highest level of recruitment (1205 patients) into research studies this year, surpassing the target of 1000 patients well ahead of time. Historically, the numbers of patients recruited to trials was around 500.



We achieved a top ten place in two categories in the National Research Activity League tables.

- the largest increase in the number of research studies opened
- the largest increase in commercial contract research studies opened

Study set-up times were reduced significantly, from 198 days to 27 days (median), and is now well below the national target and guidance.

CCC achieved 'First UK patient' recruited to studies where CCC was a participating site for ten studies (see Appendix II). We were also in the top three sites for recruitment in many interventional studies across our portfolio (see Appendix III).

CCC and the R&I Directorate have made significant contributions to help develop and establish the Liverpool Health Partners-SPARK office. Research staff developed the governance and business intelligence activity reporting systems based on our in-house system which is a national exemplar.

The Clatterbridge Cancer Charity funding call for research was re-invigorated this year. As a result, 10 research proposals led by CCC staff across a range of specialties received a total fund of £250,000. Projects selected for funding clearly articulated the wider patient benefit and will facilitate academic collaborations.

The CCC Biobank continues to expand with the highest levels of recruitment of participants this year donating samples for current and future high quality research.

We have continued to provide and expand CCC sponsorship of trials. A key strategic hepatobiliary international clinical trial sponsored by CCC is close to opening. We also have three COVID-19 CCC-led studies which are currently in set-up.

International Clinical Trials Day was celebrated across the Trust with events at CCC-Wirral and at Aintree. R&I also hosted a successful and well-received Patient and Public Involvement and Engagement event



We were finalists in the NWC CRN awards in the following categories:

- Researcher of the Year, Dr Joe Sacco and Dr Anna Olsson-Brown
- Research Rising Star of the Year, Dr Rachel Brooker
- Patient Safety Innovation, Dr Amit Patel

## Global first patient recruited to Clinical Trial at CCC

The Clatterbridge Cancer Centre was the first centre in the world to recruit a patient with a cancer affecting the central nervous system (CNS) to an early-phase clinical trial of a pioneering new therapy.

The RAGNAR clinical trial is investigating whether capsules of a drug called Erdafitinib could be an effective way of killing cancer cells caused by a rare gene abnormality.

The drug is being tested in a small number of patients with advanced solid tumour cancers which have not responded to other treatment or where the cancer has spread to other parts of the body.

The patients involved in the trial have all acquired particular abnormalities in a particular gene, the Fibroblast Growth Factor Receptor (FGFR) that is known to be involved in a number of types of cancer. It is thought that Erdafitinib binds to and inhibits FGFR, causing cancer cells to die.

Led by Professor Dan Palmer, Consultant Medical Oncologist at The Clatterbridge Cancer Centre and Director of Liverpool's Experimental Cancer Medicines Centre (ECMC), the team have become the first in the world to trial the treatment in a patient with a brain tumour known as a glioblastoma.

They have also become the first in the UK to achieve their target for the number of patients recruited to the trial, just 66 days after the study opened in February 2020.

*"Ninety-eight per cent of the patients we screen to be involved in this study are not eligible because they do not have this rare change to the FGFR gene. To have successfully recruited four patients – including the first in the world with a type of brain tumour, at the current time is an incredible achievement. This success will allow us to press ahead and continue to develop more personalised cancer treatment for patients with solid cancer tumours such as glioblastomas"*

**Professor Daniel Palmer**





## 1.4 Top three highlights each month

### April 2019

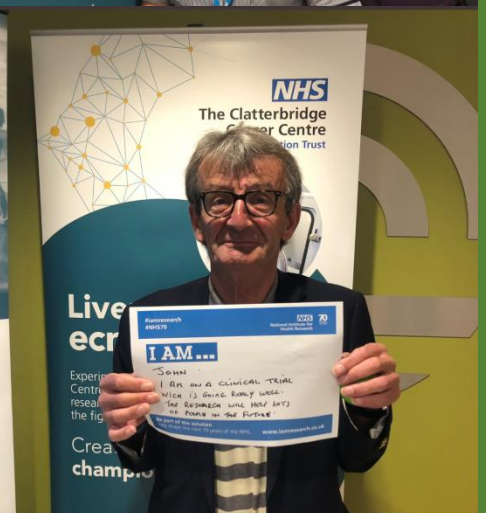
- ❖ Highest recruiter nationally for:
  - **Pivotalboost** - A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost. CI – Dr Syndikus
  - **EPOCH** - A Phase III Clinical Trial Evaluating TheraSphere® in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy. PI – Dr Montazeri
  - **Announce 2** - A Phase 1b (Open Label) / Phase 2 (Randomized Double-Blinded) Study Evaluating the Efficacy of Gemcitabine and Docetaxel With or Without a Human Anti-PDGFRα Monoclonal Antibody (Olaratumab) in the Treatment of Advanced Soft Tissue Sarcoma. PI – Dr Ali
- ❖ Highest UK recruiter and 1<sup>st</sup> UK recruit for:
  - **EPZ06438** - An Open-Label, Single Center, Two-Part, Phase 1 Study to Characterize the Pharmacokinetics of a Single Intravenous Micro-Dose of Tazemetostat (EPZ-6438) and the Absorption, Distribution, Metabolism and Elimination of a Single Oral [C] Labelled Dose of Tazemetostat in Subjects with Advanced Solid Tumours or With Lymphomas . PI – Professor Palmer
  - **Selpac** - A Randomised three-arm, open label, Phase II study of continuous Selumetinib versus continuous or interrupted Selumetinib in combination with weekly Paclitaxel in Metastatic Uveal Melanoma. PI – Dr Sacco
- ❖ CCC contributed to the Euro Ewing 2012 study. There is a high level of certainty that the trial has improved event free survival and overall survival for Sarcoma patients. CCC recruited 120% to target.

### May 2019

- ❖ ESTRO: Colleagues from Radiotherapy and Physics attended ESTRO along with 6000 delegates. CCC delivered four oral presentations (two on research), eight poster presentations and a CCC radiographer co-chaired a session
- ❖ R&I Senior Management met with colleagues from Liverpool John Moore's University to discuss the existing and future collaborative research between our two institutions. There are plans to have a workshop early July 2019 with researchers and clinicians from CCC and LJMU to explore common interests and complimentary expertise looking forward to applying jointly for funding applications.



- ❖ R&I celebrated International Clinical Trials Day 2019 with a week of events and a successful social media campaign. Members of the R&I team were present in reception at CCC Wirral and CCC Aintree with information stands to raise the visibility of research with patients and members of the public. The week ended with a staff engagement event in the R&I Building which included six stands about the different areas of R&I including: Clinical Trials, ECMC and Biobank, Qualitative Research, Research as a Career, CCC Sponsorship and Research in the new hospital.
- ❖ The social media campaign received good engagement on social media platforms including Facebook and Twitter, with a lot of users sharing their experience of research at CCC.



- ❖ The Clatterbridge Cancer Centre achieved a top ten place in two categories in the National Research Activity League tables. The categories were: the top ten trusts reporting the largest increase in the number of research studies (18 new clinical trials opened) and the top ten trusts with the largest increase in commercial contract research studies (20 studies in 17/18 and 27 studies in 18/19).
- ❖ The Myeloma team were awarded a plaque for the Clinical Service Excellence Programme by Myeloma UK. Scoring 100% in areas including Clinical Trials. The overall score was 85% which Myeloma UK said was excellent.
- ❖ The Clinical Trials Worklist went live this month in Meditech. Consultants can add patients to the worklist to alert Research Practitioners of potential patients for Clinical Trials. This was developed with colleagues in IM&T as part of the Global Digital Exemplar program to digitise clinical pathways. The worklist will be piloted in the Urology team for a period of 3 months.
- ❖ ASCO –
  - Dr Sacco – Trial in progress poster presentation for RP1 and EACH study
  - Dr Sacco is named on a poster presentation relating to IMCgp100 and potential effects on resensitisation to checkpoint inhibitors.
  - Professor Kalakonda - Update of the single-arm phase II L-MIND study of MOR208 + lenalidomide (LEN) in relapsed/refractory diffuse large B-cell lymphoma (R-R DLBCL): Response rates in patient subgroups with poor prognosis. | 2019 ASCO Annual Meeting Abstracts
  - Professor Kalakonda - Safety and efficacy of PD-L1 inhibitor durvalumab with R-CHOP or R2-CHOP in subjects with previously untreated, high-risk DLBCL. | 2019 ASCO Annual Meeting Abstracts
  - An open label, multicenter, phase I/II study of RP1 as a single agent and in combination with PD1 blockade in patients with solid tumors. | 2019 ASCO Annual Meeting Abstracts
  - Professor Palmer - NUC-1031 in combination with cisplatin for first-line treatment of advanced biliary tract cancer. | 2019 ASCO Annual Meeting Abstracts



## July 2019

- ❖ CCC are joint highest recruiters to the MARS2 Lung study nationally. The MARS2 study is a multicentre randomised trial comparing (extended) pleurectomy decortication versus no (extended) pleurectomy decortication for patients with malignant pleural mesothelioma. PI: Dr Pope.
- ❖ Clinical Trials patient John celebrated his birthday with a £6,500 donation to CCC. He had immunotherapy as part of the PRISM trial for Kidney cancer. Dr Griffiths, Chelcie Faulkner, Linda Lyons, Emma Barry and Josh Williams were invited to his party where the money was raised.

"The team treat you like a normal person; a friend, rather than a patient. You're treated with the utmost respect. I don't think you'd find better care than at The Clatterbridge Cancer Centre"

**John, Clinical Trials patient**



## August 2019

- ❖ CCC recruited the first patient into the NICO study, a CCC sponsored study. Dr Joe Sacco is Chief Investigator.
- ❖ Funding has been awarded for a study: 'Prospective observational registry and sample collection in patients with CNS involvement secondary to breast cancer' Daiichi-Sankyo: £187,000 Chief Investigator: Prof Carlo Palmieri
- ❖ Dr Anna Olsson-Brown has received a grant (£7.5k) from Northwest Cancer Research and the British Skin Foundation to run a study looking at dermatological toxicity in patients receiving immunotherapy.

## September 2019

- ❖ The first CCC patient for EV301 was consented two days after the study opened. The team recruited three patients in two months nearly meeting the recruitment target of four patients already.
- ❖ CCC have been acknowledged for contributing to a national data set in a rare tumour type where randomised studies are not possible – Small Cell bladder cancer audit. ESMO poster – Dr Eswar as author, CCC acknowledged on poster.
- ❖ PACE B study paper has been published in The Lancet Oncology and the findings were presented at ASTRO. Dr Tolan is an author.

## October 2019

- ❖ The Experimental Cancer Medicine Centre Clinic went live 21st October 2019 for all patients who are referred for early phase trials.
- ❖ Replumme 2, a Phase I dose escalation study was set up in 13 days. CCC were the first site to initiate. PI: Dr Sacco
- ❖ Alison Hassall, Advanced Research Practitioner, is co-author on a publication in the Journal of Clinical Oncology. Title: VinCaP: A phase II trial of vinflunine in locally-advanced and metastatic squamous carcinoma of the penis.

## November 2019

- ❖ The SABR Consortium took place in Harrogate which is a radiotherapy conference about SABR:
  - Dr Tony Pope was an invited speaker: “UK Lung SABR overview: How far we have come in the past 10 years?”
  - Dr Anoop Haridass was chairing at the conference
  - Louise Turtle (therapy radiographer): ‘Optimisation of SABR lung CBCT verification’ – oral presentation
  - Nicola Rankin (therapy radiographer): ‘Patient and operator compliance in the use of an abdominal compression belt’ – poster presentation
  - Kevin Fogarty (physicist): ‘Comparison of plan quality for Varian Edge 6FFF plans and Varian Truebeam 6MV plans for delivering multi-site SABR treatments’ - oral presentation.
- ❖ 400 patients have been recruited to Biobank since it started. The Biobank recruitment is higher this year to date than the whole of last year.
- ❖ Members of R&I attended the Transforming Treatment with Immuno-Oncology event in Liverpool. Drs Joe Sacco and Anna Olsson-Brown presented.

## December 2019

- ❖ CCC are the highest recruiter for the PRISM study which has now closed to recruitment. This is a study for Renal Cancer. CCC were the last site to open. 27 patients were recruited (31 patients registered) PI: Dr Griffiths
- ❖ Three poster presentations at The San Antonio Breast Cancer Symposium 2019 where Professor Palmieri is named as last author:
  - UltraSEEK Breast Cancer panel for low frequency mutation detection in breast cancer brain metastasis.
  - A systematic review of the receptor status and genomic landscape of breast cancer brain metastases.
  - The regulatory role of activating transcription factor-2 (ATF2) in modulating tamoxifen resistance in estrogen-receptor positive breast cancer.
- ❖ One podium presentation at The San Antonio Breast Cancer Symposium 2019 where Professor Palmieri was a co-author:  
'The androgen receptor is a tumour suppressor in estrogen receptor positive breast cancer'.
- ❖ Dr Griffiths has had a publication accepted in the European Journal of Cancer for the CheckMate 171 Trial. CCC were the UK's highest recruiter for this study.

## January 2020

- ❖ Dr Maria Maguire had an abstract accepted for the annual R&D Forum 2020: Faster, easier clinical research at LHP SPARK. This will be presented as a poster during the two day event.
- ❖ Drs Neeraj Bhalla and Tony Pope were invited speakers at The British Thoracic Oncology Group Meeting in Dublin 29-31 January 2020. Hala Ghos and Neeraj Bhalla also had a poster presentation: 'Audit of Safety and Tolerability of Combination Platinum-Pemetrexed-Pembrolizumab in advanced non-squamous NSCLC in the real world setting of a UK Cancer Centre'.
- ❖ ECMC team recruited the first CCC patient to the National Lung Matrix Trial in just 20 working days post SIV (PI: Dr Carles Esciu).



## February 2020

- ❖ R&I hosted a Patient and Public Involvement event - Research Matters: The next chapter. The event was a huge success with presentations from members of the R&I team and workshop discussions on how patients and the public can get involved in the work of the R&I Directorate.
- ❖ The ECMC team worked really hard to set up the RAGNAR study. The SIV was on Monday 17th February, the study was greenlighted on Friday 21st February and the first patient was consented on Monday 24th February. The patient is a young patient with brain cancer and a rare mutation who did not have many treatment options so this is a huge achievement. This patient was the first brain patient who was recruited to the study globally. This case is of significant interest to study team and beyond. (PI: Prof Palmer, Multiple disease sites).
- ❖ Dr Syndikus is named on a paper published in Clinical and Translational Radiation Oncology. Title: Evaluation of erectile potency and radiation dose to the penile bulb using image guided radiotherapy in the CHHiP trial.

## March 2020

- ❖ CCC received recognition in the March newsletter for the Optima study for being the highest recruiter.
- ❖ The Urology team received feedback from a patient who took part in the Source Trial. The patient said:  
*"Myself and my wife would like to thank Dr Griffiths and the trial team for looking after me when I joined the trial. As you can imagine, we were somewhat shell shocked and panicky after I had my kidney removed, and we didn't know how to move forward. The literature that we received about the trial was very informative and we had everything explained to us if we had any questions or concerns. At the time the actual length of the trial seemed a bit daunting, but the time flew by and I felt quite well. All in all, I had a positive experience throughout."*

## 2. Research and Innovation Directorate

The R&I Directorate has ~65 staff and is made up of the Research Delivery Team, the Research Management and Governance Team and the Research Finances Team.





## 2.1 The Research Delivery Team

**The Research Delivery Team** is led by Emma Whitby, Lead Research Nurse and constitutes the largest group in the R&I Directorate (over 50 staff in total with dedicated Research Practitioners and Clinical Trials administrators, supporting Research active consultants across the footprint of Merseyside and Cheshire). Their core functions are to:

- Deliver safe and effective care and treatment for patients participating in clinical studies.
- Support the recruitment of patients to clinical studies and provide a high quality patient experience.
- Coordinate patient care whilst on a trial, in accordance with protocol requirements
- Support Investigators through the process.
- Manage the follow up of patients on research studies and query resolution until study closure.
- Archive study documents once study is closed out by sponsor.
- The Research Delivery Team also houses Project Support Officers, Research Officers and Nursing-led research.

## 2.2 The Research Management and Governance Team

This is a cross cutting service led by Dr Maria Maguire, Research Manager. The team ensures that studies are opened safely and in a timely way with full governance oversight and quality system. Their core functions are to:

- Ensure robust research governance processes are in place for all areas including study set-up, management and oversight.
- Support academic oncology by acting as Sponsor for CCC-led studies and support the advancement of CCC-led research activity.
- Confirm the assessment of local impact for all studies taking place at site.
- Build strong relationships with pharmaceutical companies enabling our patients to access novel agents and treatments.
- Maintain and run the research biobank.

## 2.3 The Research Finance Team

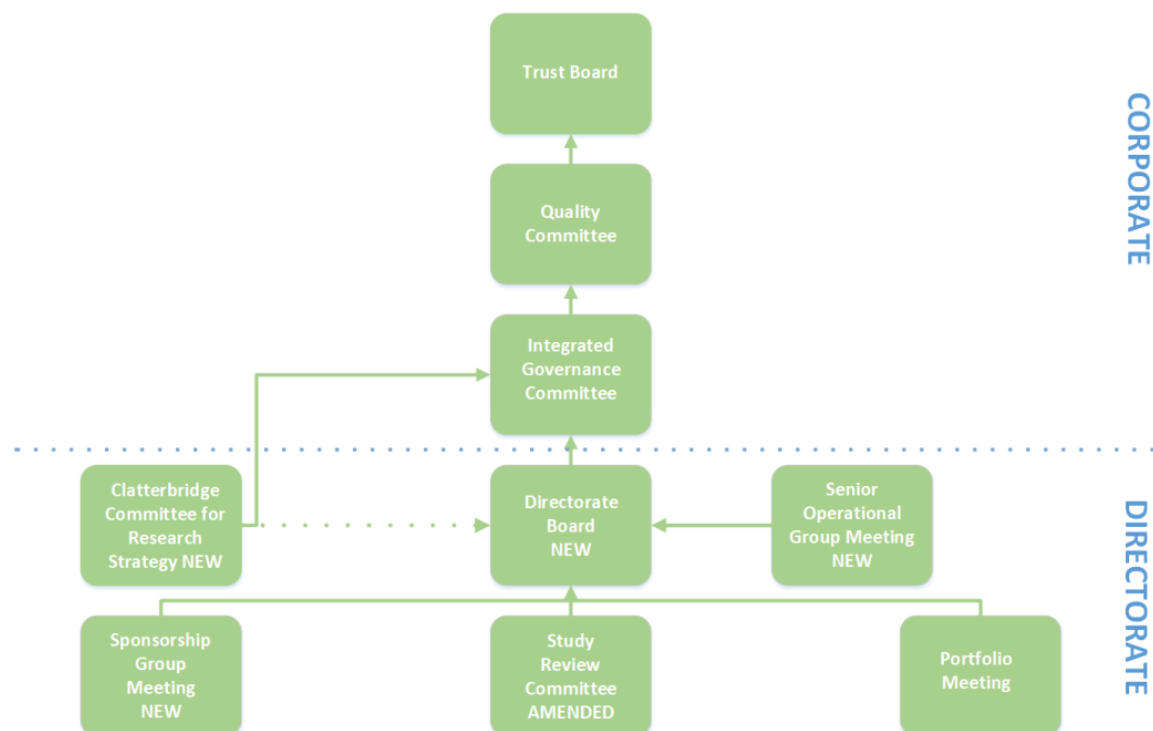
This is another cross cutting service led by Fiona Keys, Research Finance Business Manager. Their core functions are to:

- Costing and negotiation for all trials.
- Assess and report on the full resource impact of research trials at CCC.
- Ensure all invoicing for trials is carried out in a timely way.
- Grant management for all CCC-led studies

### 3. Governance Structure

In order to ensure robust management for all key functions, we have developed a new governance and reporting structure to improve productivity and outputs.

The new governance arrangements established in 2019 is shown in the diagram below. The committees now meet on a regular basis to ensure that the Directorate has robust oversight, is maximising its potential and provides forums to discuss and deliver research goals.



The four new key meetings are:

#### 3.1 Clatterbridge Committee for Research Strategy

This committee was initiated to inform, influence, develop and promote the strategic direction for R&I. It is chaired by Dr Sheena Khanduri, Medical Director and has representation from all research active areas across the Trust and external partners. This meeting will also be key to ensuring research related financial requests and bequests are reviewed transparently. The first meeting was held on 23<sup>rd</sup> July 2019 and the committee meets every two months.

#### 3.2 R&I Directorate Board

This Board will operationally manage the research strategy and the delivery outputs. It is chaired by Dr Gillian Heap, Director for R&I Operations and has operational and clinical representation from across the Trust. The first Board meeting was held on 16<sup>th</sup> July 2019 and is now convened every month.

### 3.3 Senior Operational Group Meeting

This group meets weekly and is attended by the senior research team: Director for R&I Operations (Chair), Clinical Director for R&I, Research Manager, Lead Research Nurse, Research Delivery Manager, Lead Haematology Research Nurse and Finance Business Partner. This is a proactive, issue driven meeting. Other colleagues are able to attend the meeting to present research related issues.

### 3.4 Sponsorship Group Meeting

A new Sponsorship Group Meeting has been created to ensure transparency of the decision making around CCC sponsored studies. The committee is chaired by Dr Maria Maguire, Research Manager with clinical, academic, R&I and service department representation. The committee has been meeting monthly since July 2019.

### 3.5 Other Directorate and Corporate Meetings

With the introduction of the R&I Directorate Board and the Sponsorship Committee Meeting the Research Governance Committee was removed from the structure. The Resource Committee shifted its focus to being more issue driven and was rebranded as the Study Review Committee. Finally the Portfolio Meeting remained unchanged.

The R&I Directorate provides regular reports to the Trust Board via the Integrated Governance Committee and Quality Committee. Gillian Heap is now an integral member of both these Committees to ensure that the Directorate is represented in important discussions.

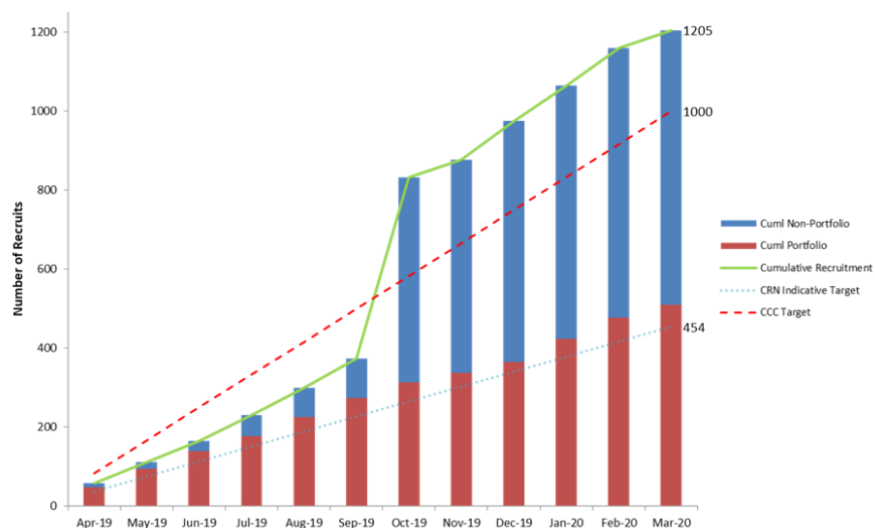
## 4. Research Operations

### 4.1 Patient recruitment

The R&I Directorate had a very successful year for recruiting participants onto research trials and studies exceeding both our internal and external targets by 20.5% and 14.1% respectively. This was as a result of streamlining the set-up process and also the introduction of weekly performance meetings and individual target setting.

	Target	Actual	% above target
Number of participants recruited to all trials.	1000 (internal)	1205	+20.5%
Number of participants recruited to portfolio trials.	454 (external)	518	+14.1%

It should be noted that 1000 participants were recruited by 22<sup>nd</sup> January 2020 which was well ahead of the target date, 31<sup>st</sup> March 2020. It should also be noted that recruitment to all trials was halted on 16<sup>th</sup> March 2020 due to the global COVID19 pandemic and the final numbers could have been higher.

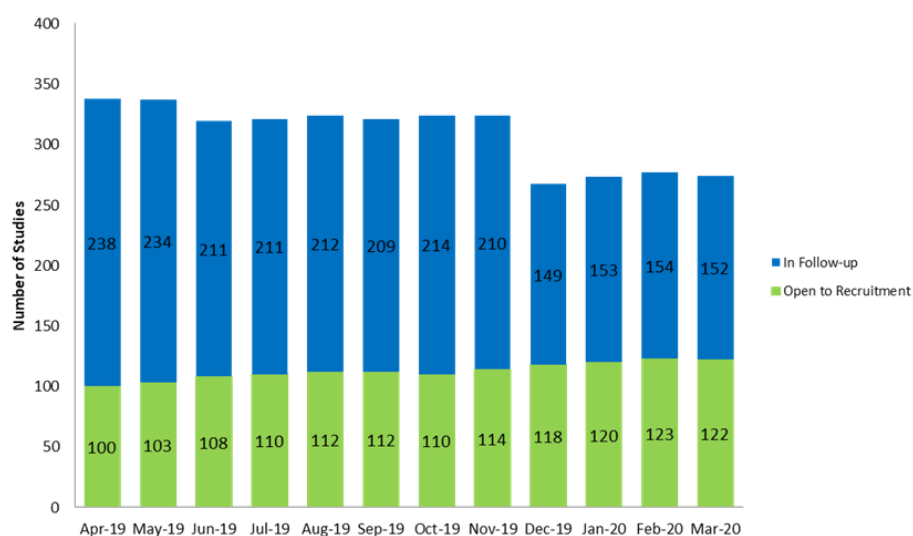


	Apr-19	May-19	Jun-19	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	16 - Mar-20
Portfolio	48	46	46	38	47	48	48	24	29	58	54	32
Non-Potfolio	10	7	9	26	23	26	410	21	69	32	41	13
Total	58	53	55	64	70	74	458	45	98	90	95	45

Breaking down the recruitment by interventional, observational and biobank it can be seen in the table below that both observational and biobank recruitment was achieved in year. The interventional recruitment was slightly under but given recruitment halted on 16<sup>th</sup> March 2020 it is anticipated that this target would have been met too if recruitment had been extended to the end of March 2020.

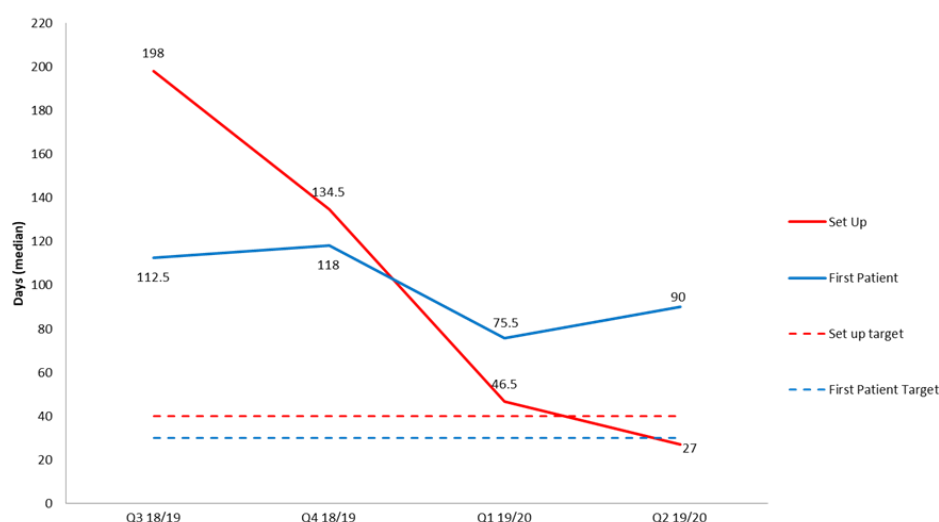
	Actual at End 03/20	Target at End 03/20	% Target End 07/19	% Target End 08/19	% Target End 09/19	% Target End 10/19	% Target End 11/19	% Target End 12/19	% Target End 01/20	% Target End 02/20	% Target End 16/03/20
Interventional	383	391	95.4	98.2 ▲	101.8 ▲	101.8 ▲	94.2 ▼	94.2 ►	96.6 ▲	101.1 ▲	98.0 ▲
Observational	608	400	46.6	51.5 ▲	48.5 ▼	212.0 ▲	190.2 ▼	183.0 ▼	173.0 ▼	162.6 ▼	152.0 ▼
Biobank	214	209	62.9	62.1 ▼	74.6 ▲	86.9 ▲	90.6 ▲	96.2 ▲	100.0 ▲	104.7 ▲	102.4 ▲
Total	1205	1000	69.0	72.0 ▲	74.8 ▲	142.7 ▲	131.5 ▼	130.0 ▼	127.9 ▼	126.5 ▼	120.5 ▼

Overall there was also a 22% increase in trials actively recruiting participants during 2019/20. This increase was mainly due to changes to improve efficiency without additional staff.



## 4.2 Set up and Delivery times

Set-up times reduced significantly during 2019/20 reducing from 196 days to 27 days (median). This is the first time we have been under the national target (n = 40 days) and we are now comparable to, if not better than, other Liverpool Trusts and UK Cancer Centres.



Set-up times were reduced by carrying out an end-to-end review of the study initiation process by both the Research Governance Team and the Delivery Teams. The process was streamlined further by identifying bottlenecks through EDGE and through process mapping. The study review process which facilitates study set-up was also re-structured and the Resource Committee was replaced by an issue-driven Study Review Committee.

Recruitment of our first patient following local site approval also reduced from 112.5 days to 90 days (median). A target of 30 days is set by the Department of Health but other cancer centres in the UK have also struggled to meet this target. Further work is ongoing to address the issues and reduce this further.

### 4.3 System changes

During 2019/20 there have been some significant system changes that have led to increased productivity. Examples of these are shown below

#### 4.31 Implementation of a new screening tool using our Electronic Patient Record system

As part of the Global Digital Exemplar programme, R&I have implemented the Clinical Trials Worklist which is a digital solution that has been developed with colleagues in IM&T. The Worklist is used to identify potential patients for a Clinical Trial at their consultation and to electronically alert Research staff via the Meditech electronic patient record.

The 'Clinical 1st Consultation' and 'Clinical FU' notes in Meditech have been amended to include a 'Trials' tab. Clinicians can access this tab in real time during a consultation to view which studies are available, along with brief eligibility criteria. If there is a potential trial for their patient, the Clinician can select the trial on Meditech which adds the patient to the Clinical Trials Worklist. Clinicians can also document if there is no suitable trial available which highlights gaps in the portfolio.

The Research Practitioners then access the Worklist to see which patients have been referred; screened and confirm eligibility and contact the patient to discuss the study. The worklist has improved visibility of research as it is integrated in the consultant annotation notes on Meditech. Consultants can easily view which studies are available for their patients and electronically refer them to the Research nursing team.

*"The ease of knowing what trials are available and ease of communication with trial nurses works well"*

**Consultant**

*"The worklist has increased the number of referrals for Clinical Trials. Consultants have referred patients for trials that they may not have previously considered"*

**Research Nurse**

#### 4.32 New Research Practitioner diary

A new Research Practitioner diary has been implemented within R&I to allow robust monitoring of patient activity and recruitment. This new tool has transformed the way the Research Practitioners function and has many benefits including:

- Reduction in transcription errors of patient identifiers, as the diary now uses a template system for inputting these parameters. In the past these had to be manually entered for each patient visit, they now only have to be entered for the patient's first visit and then the system pre-populates thereafter.
- Holds all data from July 2020 onwards, this means staff can look to one location as opposed to searching through the previous weekly sheets.
- Can be accessed through MS Teams and ensures an audit trail for changes made and has led to enhanced management oversight of all activities.
- Real time metrics are now readily available. This includes, for example, number of patients being seen by the team, number of treatments administered, and assessing how many of these are IMP on any given day/week. There is also greater flexibility to expand metrics to include splits based on Research Practitioner, HO/Solids, GTx/Oral/IV.
- Holds data across all sites, previously there were separate diaries for each site.
- Shows chemotherapy chair usage, based on the times recorded by the nursing team, the metric also builds in clean-up times between patients to ensure accuracy of reporting.

The RP diary has been designed to capture a diverse range of data, so that should any KPIs be requested, they can be easily collated and provided/presented on both retrospective (From July 2020) and prospective data sets.

#### 4.33 New Early Phase Clinical Trial clinic established

R&I have successfully established a bespoke early phase trials clinic after securing resources and space. The team ensure early phase trials are accessible to all patients in Cheshire and Merseyside many of whom have exhausted their standard treatment options. The team is raising awareness of the new service across the Trust with a monthly newsletter and has seen an increase in referrals to the clinic. The development of the early phase team has also enabled us to open and manage a larger portfolio of trials, and therefore increased the ability to offer early phase trial treatment options to our patient population.

Since the development of this service, we have been able to increase the number of patients reviewed by the early phase trials team and provide hope and alternate treatment options to patients across Cheshire and Merseyside. This service has provided a pivotal function during the current pandemic as we have continued to recruit patients to early phase trials. This has included a patient with a rare disease who was able to commence trial treatment in a targeted therapy trial, making our hospital the first site worldwide to recruit a patient with glioblastoma to this trial. This has been incredibly rewarding, as this patient was able to start a new treatment when there were no alternative standard of care options available.



#### 4.34 New Allocation roster to support staffing clinics across multiple geographical locations

A new Allocation Roster has been implemented within R&I to support the appropriate staffing of clinics across multiple geographical locations and to ensure social distancing in the office at CCC-W. The benefits of the roster are multiple as described below:

- Accessible at all times on-line, regardless of location (CCC-W, CCC-L, CCC-A or if staff are working at home).
- Staff are responsible for completing their own allocation, whereas in the past this was the responsibility of two members of the team and was completed via a paper copy.
- Ensures that a staff member's location is always known.
- Totals the number of staff intending to be in the CCC-W office to ensure appropriate social distancing.
- Contains a seating plan which can be used for desk bookings, especially if a two-metre distancing rule is to be observed. It dynamically blocks off desks as bookings are entered to ensure as many staff as possible can use their own desks while maintaining social distance.

#### 4.4 Sponsorship

A Sponsorship Group was implemented this year to strengthen the governance of clinician-led studies for which CCC acts as Sponsor. The group has clinical and service support representation. The aim of the group is to:

- Review and approve sponsorship requests for research studies which are in-line with the CCC Research Strategy.
- Review key risks of proposed studies prior to making a decision regarding sponsorship.
- Ensure adequate staffing and financial resources, appropriate systems and governance arrangements are in place to support each CCC sponsored study.
- Review quarterly CCC sponsored study metrics/compliance reports. Provide advice and recommendations on any identified issues where appropriate.

At the start of April 2019 there were three investigator-led studies open and three in set-up. By the end of March 2020 there were four studies open and five in set-up which is a good increase considering the volume of work that is required to maintain oversight and also work with the Clinical Trials Centre to manage the studies.

The three Investigator-led studies which were open at the start of April 2019 are shown below:



## Investigator-led studies open at CCC at the start of April 2019

**ACELARATE:** *A phase III, open label, multicentre randomised clinical study comparing Acelarin (NUC-1031) with Gemcitabine in patients with metastatic pancreatic carcinoma*

- Pancreatic cancer remains the most lethal of solid tumours with little progress being made to improve patient outcomes over the past 30 years of research.
- Gemcitabine has been a standard chemotherapy for these patients for more than 15 years, but drug resistance is common.
- Acelarin has been developed to overcome the resistances, which are known to limit the effect of gemcitabine and works by preventing cancer cells from dividing by attacking their DNA resulting in tumour cell death



**Prof Daniel Palmer**

**NICO:** *Neoadjuvant and adjuvant nivolumab as Immune Checkpoint inhibition in Oral cavity cancer*

- Oral cancer patients are given immunotherapy drug nivolumab. Shown to be of benefit where the cancer has spread and worsened following treatment with chemotherapy.
- This drug stimulates the immune system and when it works it often does so for a long period of time.
- Aim to assess if using this drug will reduce the chances of the cancer coming back after surgery and radiotherapy given for localised cancer, with the long term aim of curing the cancer.
- This study is also investigating whether this approach is acceptable to patients and whether adding nivolumab causes extra side effects and/or impacts on quality of life.



**Dr Joe Sacco**

**COMICE:** *Randomised Phase II Trial of Cediranib and Olaparib Maintenance in Advanced/Recurrent Cervical Cancer*

- We are looking to see if giving Cediranib and Olaparib together after patients have finished chemotherapy, can shrink or prevent the cancer from growing.
- This will be randomised against placebo and will be monitoring patients side effects, patient quality of life and patients potential life extension.



**Dr Rosie Lord**

During 2019/20 we had seven clinical academics in post. Top row from left to right:

- Professor Nagesh Kalakonda – Chair of Experimental Haematology
- Dr Joseph Sacco - Clinical Senior Lecturer in Medical Oncology
- Professor Dan Palmer – Chair of Medical Oncology
- Professor Andrew Pettitt – Chair of Experimental Medicine
- Dr John Fenwick – Clinical Physicist
- Professor Mike Brada – Chair of Radiation Oncology
- Professor Carlo Palmieri – Chair of Translational Oncology



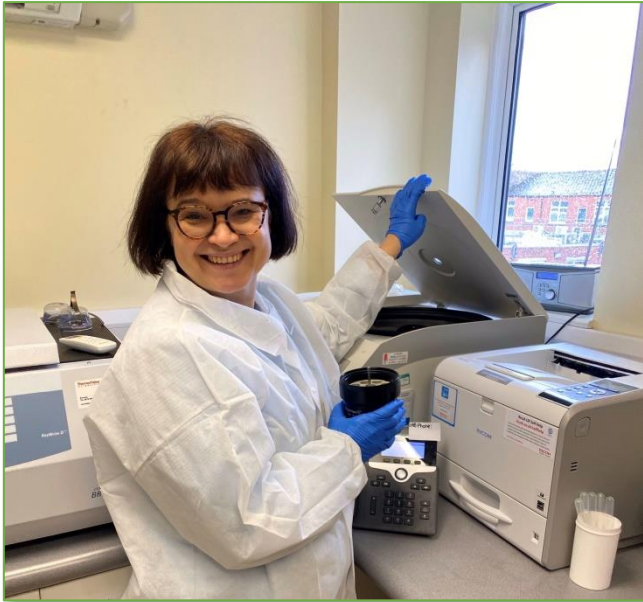
Collectively they achieved the following during 2019/2020:

- Principal Investigators on **14** new trials and **27** trials in total.
- Chief Investigators on **4** new investigator-led trials and **9** investigator-led trials in total. **8** trials of this type are currently in set-up.
- Recruited **125** patients onto clinical trials
- Recruited **214** patients into the Biobank
- Secured **£951k** of external income (commercial, non-commercial and grant related)
- Published **57** papers

## 4.5 Biobanking

The CCC Biobank provides high quality biological samples linked to patient data to facilitate:

- good quality research into the molecular mechanisms of cancer,
- biomarker discovery for early detection of cancer
- and improvement of patient outcomes.



Sample collection is entirely prospective following full informed consent from CCC patients diagnosed with cancer. The Biobank also stores samples donated from 'healthy volunteers' who have not been diagnosed with cancer in order to provide age matched controls. This year the Biobank has achieved their highest ever levels of recruitment. They recruited 214 patients against a target of 209 (102.4% of target). This was achieved via targeted sample collections, in particular supporting key research areas in Immunotherapy and mutational burden of lung cancers. These sample collections support clinician-led research in collaboration with the University of Liverpool (UoL).

## 4.6 Patient and Public Involvement

It is essential that R&I actively consults and engages with patients and carers, this is key to our refreshed Research Strategy. The R&I Directorate are committed to ensuring that patient and public involvement (PPI) is integral to all the research we facilitate.

- This year R&I held a 'Patient and Public Involvement in Research' event on 10<sup>th</sup> February 2020 at CCC-W. It was attended by nine patients and staff from R&I and the ECMC.
- Additionally a larger PPI project has been commissioned in R&I to establish a sustainable research PPI group providing training for both staff and patients.



## 4.7 Positive Feedback

Positive feedback from pharmaceutical companies, contract research organisations and our patients can be found in Appendix IV.

## 5. External partners

### 5.1 Liverpool Health Partners

We continue to engage with Liverpool Health Partners (LHP) both strategically and operationally.

- CCC R&I have contributed to multiple LHP SPARK processes and have developed the SPARK Business Intelligence system. This system links the processes together and enables cross working across organisations. The system has been commended by the LHP Executive.
- The CCC EDGE system capabilities continue to be improved and developed, to report on all aspects of R&I business intelligence. The team has been leading on the Sponsorship section of EDGE which has been extended to include site reporting and set-up.



### 5.2 Liverpool Cancer Research Institute

- In partnership with UoL and North West Cancer Research (NWCRC), CCC has played a major role in ensuring that the newly established Liverpool Cancer Research Institute is closely aligned with CCC's research agenda, commitments and goals. We are in discussions to determine the precise framework for close collaboration with a view to securing CCC Trust Board approval.



## 6. Move to Liverpool

The new CCC-Liverpool is now open and functional and the research team have seamlessly migrated their activities into the new building. We have secured four dedicated trials rooms to enhance our research capability, improve patient flow and enable greater integration with the wider Chemotherapy team.

## 7. Nursing-led Research

The R&I directorate continues to support Nurse-led research initiatives which continue to flourish.

- Two abstracts accepted at international conferences:
  - International Conference on Cancer Nursing.
  - International Society for Quality in Healthcare Conference.
- Three studies secured funding:
  - Exploring the impact of COVID-19 on the psychological well-being of oncology healthcare professionals.
  - Reducing Emergency Admissions for Patients with Cancer Complications and/or Co-morbidities.
  - Gynaecological Cancer Narratives study.
- Our nursing staff have supervised external PhD students conducting their research at CCC:
  - An exploration of stories of people who are end of life aged 16-24 years using Narrative analysis (Manchester Metropolitan University).
  - Examining the psychological impact of childhood cancers on young adults and their life experiences (Edge Hill University).
  - Re-testing the initial effectiveness of ACTION for stress-management: an Acceptance and Commitment Training Intervention for Oncology Nurses (University of Chester).
- Three publications based on research completed at CCC:
  - A Study of Childhood Cancer Survivors' Engagement with Long-Term Follow-Up Care: 'To attend or not to attend, that is the question' – European Journal of Oncology Nursing.
  - Peer mentors for people with advanced cancer: lessons learnt from recruiting and training peer mentors for a feasibility randomised controlled trial – Journal of Cancer Education.
  - Peer support to maintain psychological wellbeing in people with advanced cancer: Findings from a feasibility study for a Randomised Controlled Trial - BMC Palliative Care.

## 8. Social media content/press releases

We have improved the visibility of our research both internally and externally by posting a steady stream of research content on social media platforms, through the CCC accounts and personal accounts of staff members. News worthy stories or achievements are shared and have been widely acknowledged and facilitated collaborations.

Examples of popular posts from 2019/20 are shown below:





**ClatterbridgeCC NHS** ✓ @CCCNHS · 22/08/2019

Our Director of Research & Innovation Operations, @Gillianheap5 along with our Medical Director @Docsheenak and Chief Executive @LizBishopCCC sat down with @NIHRCRN\_nwcoast earlier today for a very productive meeting exploring opportunities that will benefit our patient outcomes



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**Gillian Heap** @Gillianheap5 · 03/10/2019

Big congratulations to Linda & Sue who attended the staff Long Service Awards @CCCNHS yesterday. Linda has worked at the Trust for 20 years & Sue for 10 years!! They both currently work in #research in nursing & finance, we couldn't be prouder of them! #dedication #loyalty



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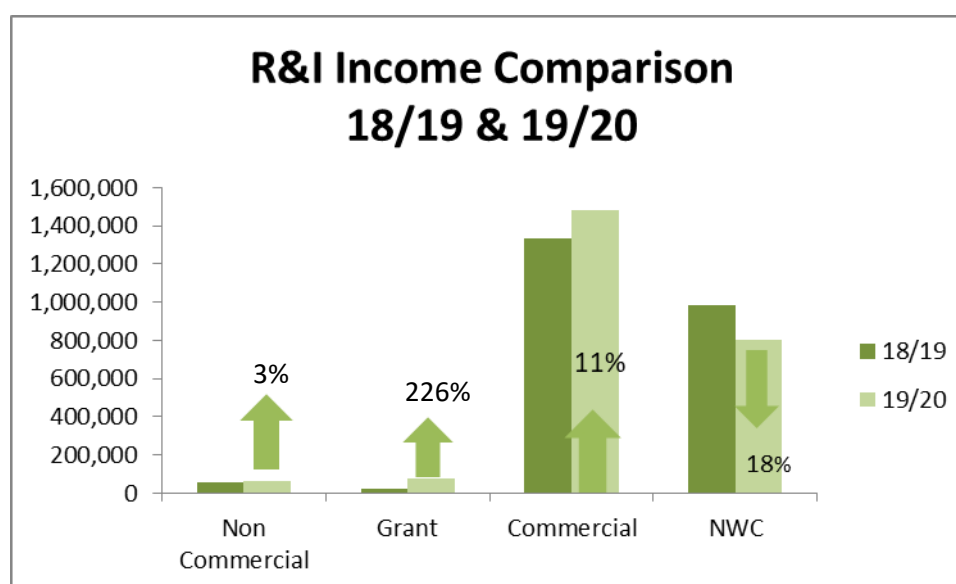


## 9. R&I Financial Report 2019/20

During the financial period April 2019 - March 2020, the R&I Directorate saw an overall increase of income in relation to solid tumours, with the exception of NWC CRN funding which decreased by 18% to £802kpa from £983kpa in the previous financial period.

The table and graph below show the income comparison for the two financial periods for the R&I Directorate:

Funding Stream	18/19	19/20	Variance
<b>Non Commercial</b>	57,959	59,465	1,506
<b>Grant</b>	23,000	75,000	52,000
<b>Commercial</b>	1,335,394	1,485,153	149,759
<b>NWC</b>	982,594	801,815	(180,779)
<b>Total</b>	<b>2,398,946</b>	<b>2,421,433</b>	<b>22,486</b>



### 9.1 Clatterbridge Funding Research Scheme 1920 – Charity Funded Research Studies

In 2019/20 £250k was awarded to support collaborative research projects. The scheme aimed to foster partnership working within the organisation and/or with academic/pharmaceutical partners. The scheme attracted wide interest and multiple high-quality applications. Details of the ten successful applications can be found in Appendix V.

## 10. COVID-19

In March 2020, understanding how clinical research at CCC and the R&I directorate could support initiatives to tackle the COVID-19 pandemic was unclear. As a tertiary cancer centre we had no access to ITU or HDU services. There was also limited guidance on how to protect our vulnerable patients. The options available were to pause trials, which happened on 16<sup>th</sup> March 2020 and shield our patients unless they needed essential treatments.

The Research Team recognised the urgent need to be reactive in such unique and challenging circumstances. Introduction of an inclusive weekly virtual COVID-19 Research meeting was initiated.

The purpose was to:

- Review the open portfolio of COVID-19 studies and pragmatically select a subset we could contribute to, in order to gain knowledge from and for our cancer patients.
- Explore our own investigator-led research relevant to our cancer patient pathways.
- Provide funds for COVID-19 research addressing issues related to and impacting cancer patients
- Explore the impact of COVID-19 on our staff.

In addition, CCC was represented regionally at the Liverpool Health Partner (LHP) COVID-19 meetings and at the North West Coast Clinical Research Network COVID-19 meetings.

The COVID-19 pandemic has had a significant negative impact on cancer patients. Although in their best interests, pausing treatment to help protect our patients has undoubtedly caused both physical and psychological stress. Recovery and reset of our cancer trials is now well underway to support our patients. We have made significant contributions to COVID-19 research and contributed to urgent public health national studies.

## 11. Innovation

An important ambition of the R&I directorate is to improve the innovation agenda at CCC. There are pockets of excellence of innovation around the Trust but they are not currently captured in a structured way. Once the R&I Research Strategy has been approved and operational plans are in place, a standalone Innovation Strategy for the Trust will be developed.

- An Intellectual Property Policy has been drafted and is currently under review.
- Meetings with Liverpool Health Ventures and other NHS Trusts across Liverpool including CCC have been held to discuss the development of a sustainable health innovation accelerator with early stage funding for NHS innovations, start-ups and University spin-outs.



## Appendix I – Site Reference Group Research Leads

Site Reference Group	Research Lead
Breast	Dr Rosa Guiliani
CNS	Dr Shaveta Mehta
Gynae	Dr Danielle Shaw
Head and Neck	Dr Anoop Haridass
Haematology	Professor Nagesh Kalakonda
Lower GI	Dr Victoria Shallcross
Lung	Dr Carles Escriu
Skin/Melanoma	Dr Joe Sacco
Specialist (Testicular/Paeds/TYA/Sarcoma)	Dr Farida Alam
Upper GI and HPB	Dr Olusola Faluyi
Urology	Dr Chinnamani Eswar



*“The role of SRG Research Lead helps to provide a strong emphasis on research in the Urology SRG. The role provides a good link between the research team and Urology clinicians”*

**Dr Eswar, Urology SRG Research Lead**

*“The introduction of this post is an important step to enable prioritisation of studies and to take a strategic view on how the portfolio can develop to maximise impact”*

**Dr Sacco, Skin/Melanoma SRG Research Lead**



## Appendix II - Trials where CCC is the first national recruiter

Project Acronym	Project Full title	Principal Investigator	Disease Group
MO40653 IMREAL	A Non-Interventional, Multicenter, Multiple Cohort Study Investigating The Outcomes And Safety Of Atezolizumab Under Real-World Conditions In Patients Treated In Routine Clinical Practice	Dr Isabel Syndikus	A Select Disease Group Type
BEIGENE AME – BGB—290- 106	A Phase 1 Study to Investigate the Absorption, Metabolism, and Excretion of [14C] Pamiparib following Single Oral Dose Administration in Patients with Advanced and/or Metastatic Solid Tumors	Prof Daniel Palmer	Upper GI
P2D	Digital Support for Living With and Beyond Gynaecological Cancer	Lynda Appleton	Gynaecological
PROACT	PROACT communication: Patient Reported Opinions About Clinical Tolerability Empowering patients participating in early oncology studies and providing a way for them to directly contribute to drug development on their own terms.	Prof Daniel Palmer	Other
BGB-290- 303	A Phase 3, Double-blind, Randomised Study of BGB-290 versus Placebo as Maintenance Therapy in Patients with Inoperable Locally Advanced or Metastatic Gastric Cancer that Responded to Platinum-based First-line Chemotherapy.	Dr Ayman Madi	Upper GI
JCAR017 Real-World Study	A Non-Interventional, Retrospective, Multi-Center Study To Generate Real-World Evidence Of Treatment Outcomes In Subjects With Relapsed/Refractory Aggressive B-Cell Non-Hodgkin Lymphoma	Prof Nagesh Kalakonda	Haematological
NUTIDE 121	A Phase III Open-Label, Multi-Centre, Randomised Study Comparing NUC-1031 plus Cisplatin to Gemcitabine plus Cisplatin in Patients with Previously Untreated Locally Advanced or Metastatic Biliary Tract Cancer	Prof Daniel Palmer	Upper GI
LECMC Biomarker Discovery	Liverpool Experimental Cancer Medicine Centre (LECMC) Biomarker Discovery Programme and Prospective Sample Collection	Prof Daniel Palmer	A Select Disease Group Type
CAcTUS	A parallel arm, biomarker driven, phase II feasibility trial to determine the role of circulating tumour DNA in guiding a switch between targeted therapy and immune therapy in patients with advanced cutaneous melanoma	Dr Shien Chow	Melanoma
CA209-8KX	Phase I/II pharmacokinetic multi-tumor study of subcutaneous formulation of nivolumab monotherapy	Prof Daniel Palmer	A Select Disease Group Type

### Appendix III - Trials where CCC is the highest national recruiter

Project Acronym	Project Full title	Principal Investigator	Disease Group
<b>HYST</b>	Hypersensitivity Study: A Mechanistic Investigation into Drug and Chemical Induced Hypersensitivity Reactions	Dr Rosie Lord	Different cohorts
<b>rEECur</b>	International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	Dr Nasim Ali	Sarcoma
<b>PATHOS</b>	A Phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV)-positive oropharyngeal cancer	Dr Aditya Shenoy	Head & Neck
<b>ACELARATE</b>	A phase III, open label, multicentre randomised clinical study comparing Acelarin (NUC-1031) with Gemcitabine in patients with metastatic pancreatic carcinoma (ACELARATE: Acelarin first line randomised pancreatic study)	Prof Daniel Palmer	Upper GI
<b>ABC-07</b>	Addition of stereotactic body radiotherapy to systemic chemotherapy in locally advanced biliary tract cancers	Dr Rajaram Sripadam	Upper GI
<b>OUTREACH</b>	A First-in-Human, multi-centre, open-label, Phase 1 clinical study with RNA oligonucleotide drug MTL-CEBPA to investigate its safety and tolerability in patients with advanced liver cancer (OUTREACH)	Prof Daniel Palmer	Upper GI
<b>RDSI</b>	A randomised controlled trial to determine the clinical and cost effectiveness of the Respiratory Distress Symptom Intervention for people with lung cancer	Dr Carlos Escriu	Lung
<b>COMICE</b>	A randomized double blind placebo controlled Phase II clinical trial of Cediranib and Olaparib maintenance in advanced recurrent Cervical Cancer.	Dr Rosie Lord	Gynaecological
<b>OPERA</b>	European phase III study comparing, in association with neoadjuvant chemoradiotherapy, a radiation dose escalation using 2 different approaches: External Beam Radiation Therapy versus endocavitary Radiation Therapy with Contact XRay Brachytherapy 50 kV for patients with rectal adenocarcinoma cT2-T3 a,b < 5cm in diameter in distal and middle rectum	Dr Sun Myint	Colorectal
<b>PRISM</b>	A randomised phase II trial of nivolumab in combination with alternatively scheduled ipilimumab in first-line treatment of patients with advanced or metastatic renal cell carcinoma	Dr Richard Griffiths	Renal
<b>PIVOTAL-boost</b>	A phase III randomised controlled trial of prostate and pelvis versus prostate alone radiotherapy with or without prostate boost	Dr Isabel Syndikus	Prostate

Project Acronym	Project Full title	Principal Investigator	Disease Group
<b>CYTOFLOC</b>	Evaluation of a Non-Endoscopic Immunocytological Device (Cytosponge) for post chemo-radiotherapy surveillance in patients with oesophageal cancer – a feasibility study	Dr Rajaram Sripadam	Upper GI
<b>ONCORE</b>	Oncological Outcomes after Clinical Complete Response in Patients with Rectal Cancer	Dr Rajaram Sripadam	Other
<b>Show Respect</b>	Show RESults to Participants Engaged in Clinical Trials	Dr Rosie Lord	Gynaecological
<b>Real World study of EPR and HCRU</b>	Observational, retrospective real-world evidence study of adult advanced non-small cell lung cancer patients treated with first-line therapy to determine treatment pathways, survival outcomes and healthcare resource utilisation in routine clinical practice in the UK	Dr Carlos Escriu	Lung
<b>MO40653 IMREAL</b>	A Non-Interventional, Multicenter, Multiple Cohort Study Investigating The Outcomes And Safety Of Atezolizumab Under Real-World Conditions In Patients Treated In Routine Clinical Practice	Dr Isabel Syndikus	A Select Disease Group Type

#### Appendix IV - Feedback from Pharma/CRA/Patients

**Thank you to Dr Griffiths and Chelcie Faulker, Senior Research Practitioner from David Eva, Chariman of Lancashire Care FT and Chair of Healthy Wirral.**

*"I just wanted to pass on a compliment about the service received by a close relative from Liverpool who has had a trial drug treatment at CCC. Gerry is in his 70's has always worked and kept fit and like many of his ilk shrugged off pains until his family demanded he go and get tested only to find advanced cancer. He was fortunate to be offered an immunotherapy trial that has been remarkably effective although the journey was very rough. He cannot praise all the staff highly enough and in particular his consultant Dr Griffiths and a nurse (Chelcie) whose compassion, dedication and care gave him the strength to keep going when he was about to give up. Chelcie is obviously the sort of nurse we need to clone thousands of!! Please pass on the families warmest gratitude to all those concerned."*

**Thank you from the EFACCT team complimenting Lynda Appleton, Research Nurse and Hannah Doughty, Research Officer on their commitment to the study**

*"I would like to extend my warmest thanks for the considerable support that you have provided to the EFACCT study, both as a site and yourselves as individuals. To date The Clatterbridge Cancer Centre has been the largest recruiter to the study and the depth of contribution from the participants has been tremendous. I am indebted to you all for the incredible commitment you have all made to the research"*

**Dr Lynda Appleton, Research Nurse, received a certificate of thanks for her review contributions to European Journal of Cancer Care**

*"We depend on the efforts and integrity of our reviewers to examine each submitted manuscript and render an opinion as to its suitability for publication. With the attached certificate we would like to express our gratitude for your activity, which is very much appreciated by the Editors and Editorial Board of the journal"*

**During June 2019 CCC was the highest recruiter to Selpac in the UK. The sponsor thanked Hollie Wilson, Data Manager and Barbara King, Senior Research Practitioner for their hard work reaching the data-lock:**

*"On behalf of myself and Kayley, please let me say a BIG **thank you** for all your help and hard work in preparation for the SelPac primary analysis data-lock. We will go into the data-lock with the below figures for Clatterbridge (1 outstanding query, 1 outstanding CRF), this is amazing, even more so when considering the number of patients Clatterbridge have recruited.  
(to note the outstanding query and CRF do not relate to any primary end-point data)."*

**Nick Garbutt, Data Manager, received some positive feedback from a CRO for the CARRICK CT7001 Study. They said:**

*"Your coordination and management of this process from Trust perspective was full of thought and care. Much appreciated"*

**The Research Nurses received a card from a Research Patient who said:**

*"To all my lovely nurses, have a wonderful Christmas and a very happy new year. Thank you all so much for all the care you give to me also for the support.  
You are all so kind."*

## Appendix V – Successful applications to The Clatterbridge Research Funding Scheme (CRFS)

CRFS 19/20 Approved Bids	Lead Applicant(s)	£
Characterization of exosomal nc-RNA as surrogate biomarker of response to TKI in EGFR positive lung cancer patients	Dr. Carles Escriu	20,000
Radiomics based PET-CT image analysis to predict tumour heterogeneity & therapy responses	Dr. Indrani Karpha	30,000
Analysis of association between Cox-2 expression and primary resistance to checkpoint inhibitor therapy for cancer	Dr. OO Faluyi	30,000
Reducing Emergency Admission for Patients with Cancer Complications and/or Comorbidities	Dr. Lynda Appleton	25,000
Exploiting National Cancer Datasets to understand real-world variations in practice	Dr. Umair Khan	20,000
Microbiome as a potential biomarker of response in locally advanced oral cavity cancer	Dr. Rachel Brooker	19,872
Feasibility of fast imaging methods for whole body AI-assisted screening in MRI	Dr. Marc Rea	20,000
MRI Guidance for lung radiotherapy	John Fenwick, Michael Brada and Mark Warren	25,000
Examining the Impact of FLASH proton beam therapy	Dr. Jason Parsons	30,000
Confocal Endomicroscopy for pre-clinical detection of checkpoint inhibitor induced colitis	Dr A Olsson-Brown	30,000
	<b>Total Awarded</b>	<b>249,872</b>



## What Research means to us...

Research & Innovation CCC 