

Limerick Cancer Trials Group

Director of Limerick Cancer Trials Group – Professor Ruth Clifford

Co-Director Limerick Cancer Trials Group – Dr Niamh Peters

ADON/Clinical Operations Manager, Limerick Cancer Trials Group – Ms
Maureen O’Grady

Finance & Senior Administration Manager – Ms Michelle Meade O’Sullivan

Who are our staff LCTG

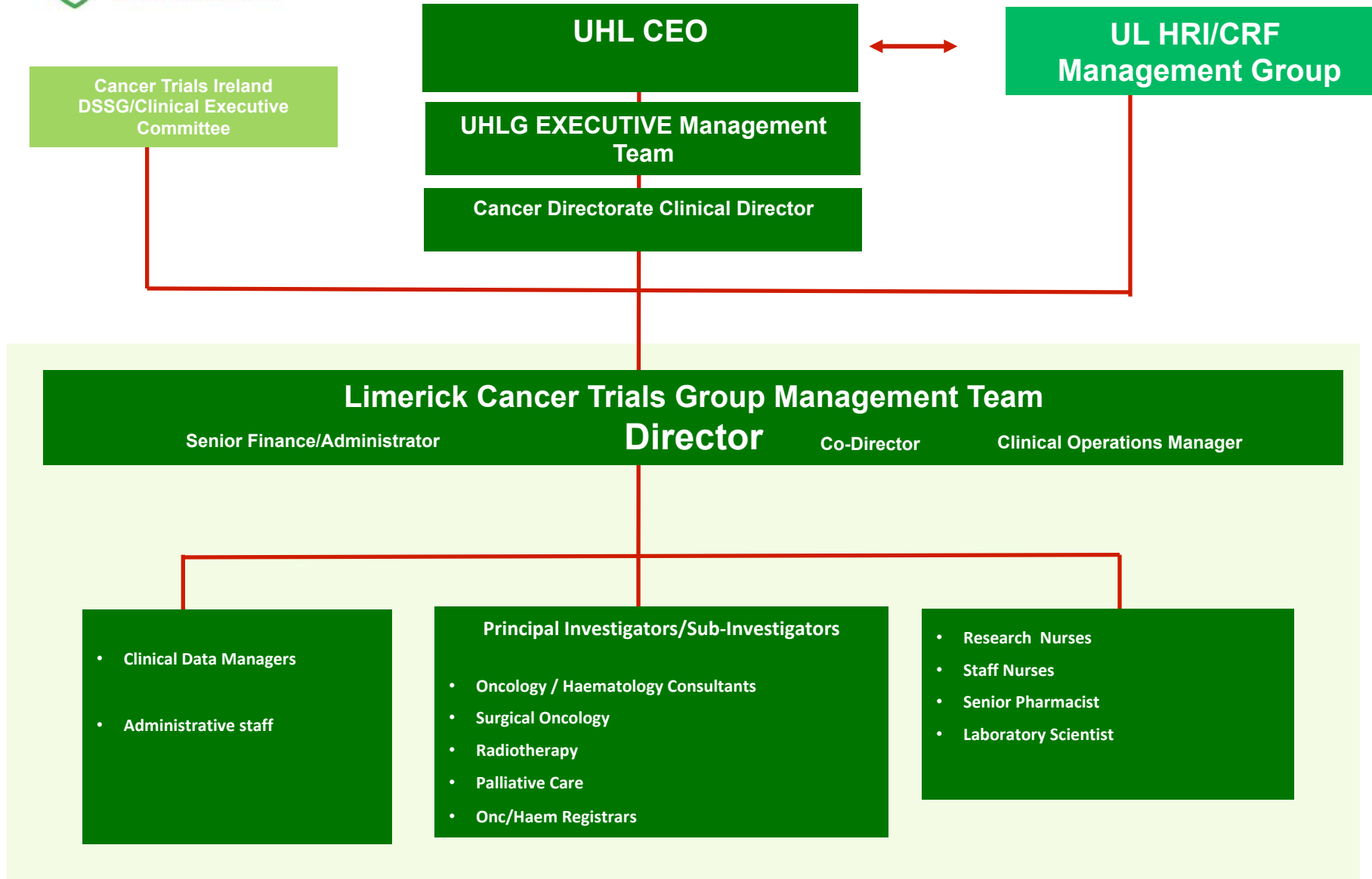
- 1 x Clinical Director – Professor Ruth Clifford, Consultant Haematologist
- 1 x Co-Director – Dr Niamh Peters, Consultant Medical Oncologist
- 4 x Haematology PIs – Dr Hilary O’Leary; Dr Denis O’Keeffe; Dr Aisling Nee; Dr Cian McEllistrim
- 4 x Oncology PIs – Dr Niamh Peters; Dr Greg Korpanty; Dr Roshni Kalachand; Dr Nemer Osman
- 2 Radiotherapy PIs – Dr Lorraine Walshe, Dr Mazen El Bassiouni
- 1 x Clinical Operations Manager (study start up) – Ms Maureen O’Grady
- 1 x Finance & Senior Administration Manager – Michelle Meade O’Sullivan
- 1 x CNM III (quality, education and training) – Ms Lorraine O’Connell
- 5 x CNM II – Heather Coffee Jones; Elaine McCarthy; Clora O’Connor; Geraldine Madigan; Helena McCallig
- 2 x Clinical Data Managers – Ms Siobhan O’Brien; Ms Ciara Cantrell
- 1 x Grade IV Clerical Officer ; Ms Ela KoronaAnsari

LCTG Training Day



Limerick Cancer Trials Group

- LCTG Management Team
- Membership: Prof Ruth Clifford, Dr Niamh Peters, Ms Maureen O'Grady, Team Leader LCTG, UHL; Ms Valerie Madigan, Business Manager, Cancer Directorate, UHL; Ms Michelle Meade O'Sullivan, Cancer Directorate Management Team: Manages inpatient and outpatient Cancer Services
- Cancer Services Directorate
- Membership: Dr Denis O'Keeffe, Chairperson, Clinical Director Cancer Directorate, UHL; Ms Mairead Cowan, Director of Nursing for Cancer Directorate and Research Nursing, UHL; Ms Breda Duggan, General Manager Cancer Directorate, UHL; Mr Tadhg Murnane, Senior Finance Manager, Cancer Directorate, UHL; Professor Ruth Clifford, Associate Clinical Director, UHL.



Recruiting Trials open in UHL

Breast Recruiting Trials

- **Trial Name:** SASCIA
- **Trial Number:** 20-24
- **Patient profile:** Her 2 - breast cancer patients in post neoadjuvant setting
- **Purpose:** Phase III postneoadjuvant study evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in primary HER2- negative breast cancer patients with high relapse risk after standard neoadjuvant treatment'
- **Trial Name:** Destiny – Breast05
- **Trial Number:** 21-15
- **Patient Profile:** HER2-positive primary breast cancer who do not achieve complete response after appropriate neoadjuvant therapy and are at higher risk of disease recurrence.
- **Purpose:** This study will examine the efficacy and safety of trastuzumab deruxtecan (T-DXd) compared with trastuzumab emtansine (T-DM1) in high-risk patients with residual invasive breast cancer following neoadjuvant therapy.
- <https://healthservice.hse.ie/healthcare-delivery/ul-hospitals-group/cancer-clinical-trials/>

Lymphoma and Blood Cancer Recruiting Trials

- **Trial Name:** MK1026-003
- **Trial No:** 2020-002324-36
- **Patient Profile:** Participants with CLL, Richey's transformation, non-Hodgkin lymphoma and Waldenstrom's macroglobulinaemia
- **Purpose:** A phase II study to evaluate the safety and efficacy of ML1026-003 in participants with haematologic malignancies
- **PI:** Professor Ruth Clifford
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- **Trial Name:** ANT-007
- **Trial No:** 2021-003026-14
- **Patient Profile:** Patients with cancer associated VTE (ASTER)
- **Purpose:** A multicentre, randomised, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to apixaban on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE (ASTER)
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- **Trial Name:** ANT-008
- **Trial No:** 2021-003085-12
- **Patient Profile:** Abelacimab versus dalteparin in the treatment of GI/GU cancer and associated VTE
- **Purpose:** A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to dalteparin on venous thromboembolism (VTE) recurrence and bleeding in patients with gastrointestinal (GI)/genitourinary (GU) cancer associated VTE (Magnolia)

Lymphoma and Blood Cancer Recruiting Trials contd

- **Trial Name:** Isa-RVD
- **Trial Number:** 19-34
- **Patient Profile:** The target population for this study are patients with newly diagnosed multiple myeloma for high dose therapy and autologous stem cell transplant. Patients will have a confirmed diagnosis of multiple myeloma, based on standard IMWG criteria.
- **Purpose:** This study is a Phase II, multi-centre, single-arm, open-label study to evaluate the efficacy and safety of the combination regimen Isatuximab, Lenalidomide, Bortezomib, and Dexamethasone in patients with newly diagnosed multiple myeloma.

- **Trial name:** BCBI (Blood Cancer Biobank Ireland) sample collection
- **Trial number:** n/a
- **Patient profile:** Suspected or newly diagnosed or relapsed but not on treating patients with CLL, AML or Multiple Myeloma.
- **Purpose:** Collection of bone marrow or peripheral blood samples to be stored in a biobank for use in current or future research.

Lymphoma and Blood Cancer Recruiting Trials contd

- **Trial name:** The Impact of Genetic Expression Profile on Depth of Response and Survival in Myeloma (MRD Study)
- **Trial number:** n/a
- **Patient profile:** Patients who have been diagnosed with multiple myeloma and are potentially eligible for autologous stem cell transplant.
- **Purpose:** Prospective, non-interventional, observational study to evaluate the combined assessment of gene expression profiling and MRD analysis to determine impact of genetic risk on achievement of MRD negativity and PFS in newly diagnosed transplant eligible patients with Multiple Myeloma receiving standard of care regimens
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- **Trial name:** Natural and Vaccine-induced Immunity to COVID-19 in Haematological Malignancies
- **Trial number:** n/a
- **Patient profile:** Patients with blood cancers who are undertaking the COVID-19 Vaccine or who have had a COVID-19 infection to understand if there is a response to the vaccine/infection.
- **Purpose:** This is a study on the immune response of patients with blood cancers who are undertaking the COVID-19 vaccine or who have had a COVID-19 infection to understand if there is a response to the vaccine/infection. We know that not all patients with blood cancers will have a normal response to vaccines such as the influenza vaccine.
- For this reason, more information is needed to understand the immune response of patients with blood cancers. We will be studying blood samples taken ideally before and after vaccination and testing different parts of the immune system to see if, compared to people without blood cancer, the immune response is different.
- Please remember, that these are research tests and their results will not impact your treatment, but we hope that this project will help us to understand how patients will respond to COVID-19 infection and vaccination. This may lead to improved protective measures against COVID-19 in the future for patients.

Lung Cancer Recruiting Trials

- **Trial Name:** Latify
 - **Trial No:** 2022-000493-26
 - **Patient Profile:** Lung cancer
 - **Purpose:** A Phase III, open-label, randomised, multicentre study of Ceralasertib plus Durvalumab versus Docetaxel in patients with advanced or metastatic non-small cell lung cancer without actionable genomic alterations, and whose disease has progressed on or after prior Anti-PD-(L) Therapy and platinum-based chemotherapy.
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- **Trial Name:** Plan Study – Translational Study
 - **Trial No:** 006/2023
 - **Patient Profile:** Plasma Genomic testing in patients with advanced non-small cell lung cancer
 - **Purpose:** To establish the feasibility of liquid biopsies for genomic diagnosis and targeted therapy selection in patients with advanced lung cancer.

Oncology studies site selected – in set up

MIRATI-7	2020-003101-58	Dr Greg Korpanty	MIRATI 7 - A phase 2 t	Lung	Interventional	Set-up	Regulated	Clinical trial	Phase II
ADEPPT - ETOP 22	2022-002736-31	Dr Greg Korpanty	A multicentre, single	Lung	Interventional	Set-up	Regulated	Clinical Trial	Phase III
SHAMROCK	2022-002485-32	Dr Greg Korpanty	Single arm phase II tri	Breast	Interventional	Set-up	Regulated	Clinical Trial	Phase II
PEACE 6		Dr Greg Korpanty	Frail men with hormo	GU	Interventional	Set-up	Regulated	Clinical Trial	Phase III
CADDY SUBSTUDY	CTRIAL -08-01	Dr Greg Korpanty	Analysis of biomarker	Breast	Observational	Set-up	Regulated	Clinical trial	Other
BREAST BIOBANKING		Dr James Brown UL	Tissue donation from	Breast	Biobanking	Set-up	Regulated	Clinical trial	Other
ARC 10		Dr Greg Korpanty	Phase III study to eval	Lung	Interventional	Set-up	Regulated	Clinical Trial	Phase III
DeEscalate EORTC	2023-506817-23	Dr Niamh Peters	Intermittent Androge	Prostate	Interventional	Set-up	Regulated	Clinical Trial	Phase III
CUPan	CTRIAL - IE 2308	Dr Niamh Peters	Registry for Carcinom	Unknown primary	Registry	Set-up	Regulated	Clinical Trial	N/A

Haematology Studies site selected – in set up

PETReA	2016-004010-10	Dr Hilary O'Leary	A phase III evaluation	Set-up	Regulated	Clinical Trial	Phase III
HH Blood		Professor Ruth Clifford	Blood donations of pa	Set-up	Regulated	Clinical Trial	Other
CLL Fantom		Professor Ruth Clifford	Exploring the landsca	Set-up	Regulated	Clinical Trial	Other
E Health Hub		Professor Ruth Clifford	The national Cancer Strategy identified an urgent need for frameworks that increase finable, accessible, interoperable and reusable (FAIR) sharing of health data and stated it was a major obstacle in measuring performance and evidence based policy decisions.	Set-up	Regulated	Clinical Trial	Other
Tonsil		Professor Ruth Clifford	Tonsil Tissue as a sou	Set-up	Regulated	Clinical Trial	Other
AluMMinate - 1 trial	2022-501530-34-00	Professor Ruth Clifford	A phase 3 randomised	Set-up	Regulated	Clinical Trial	Phase III

Feasibilities submitted – awaiting site selection

Harmoni 3		Dr Greg Korpanty	A randomised, double	Set-up	Regulated	Clinical Trial	Phase III
Eternity Registry		Dr Greg Korpanty	This is a prospective a	Set-up	Regulated	Clinical Trial	Other
DeEscalate EORTC		Dr Niamh Peters	Intermittent Androge	Set-up	Regulated	Clinical Trial	Other
Regeneron Lung Study		Dr Greg Korpanty	A phase II to III study	Set-up	Regulated	Clinical Trial	Phase II/III
Retrospective data collection		Prof Ruth Clifford	Hodgkin lymphoma in older patients (HoOP-EHA) - a European retrosepctive study.	Set-up	Regulated	Clinical Trial	Other
Cambria 2		Dr Roshni Kalachand	A phase III, open labe	Set-up	Regulated	Clinical Trial	Phase III
Flamingo 01		Dr Greg Korpanty	OPTIMA YOUNG - opti	Set-up	Regulated	Clinical Trial	Other
Parexel/Menarine		Dr Greg Korpanty	Investigational study	Set-up	Regulated	Clinical Trial	N/A
Parexel 275125		Dr Greg Korpanty	Genomic screening at	Set-up	Regulated	Clinical Trial	N/A
Eli Lilly Ember 4		Dr Greg Korpanty	To evaluate the effica	Set-up	Regulated	Clinical Trial	N/A
GS-US-592-6173		Dr Greg Korpanty	A randomised, open l	Set-up	Regulated	Clinical Trial	Phase III

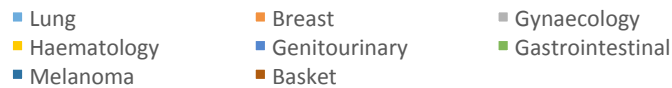
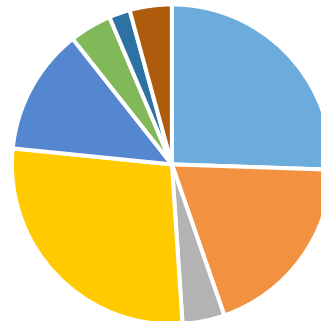
Clinical Trial Activity

- To date, we have enrolled 473 patients in 46 studies since 2017.
- This year, we have opened 8 new studies in the areas of lung, breast and blood.
- We were the top recruiter nationally for ISA-RVD Multiple Myeloma study – and 2nd highest nationally for CLL.
- HPRA Inspection in February 2023 with no critical events noted.

LCTG Cancer Trials, UHL Graphical Analysis by disease area 2017-2023

Lung	12
Breast	9
Gynaecology	2
Haematology	13
Genitourinary	6
Gastrointestinal	2
Melanoma	1
Basket	2

Chart Title



LCTG Accruals 2017-2023

MONTHLY ACCRUAL 2016-2018	2016	2017	2018	2019	2020	2021	2022	2023
Jan	0	2	0	5	5	9	13	3
Feb	0	1	4	7	12	12	12	0
Mar	0	2	0	10	4	17	14	2
Apr	0	0	1	7	1	5	6	4
May	0	0	2	5	1	11	9	10
Jun	0	9	2	3	3	15	16	8
Jul	0	8	2	4	3	6	1	2
Aug	0	4	6	2	4	12	4	1
Sep	0	6	8	0	12	34	3	3
Oct	0	16	5	2	6	15	2	24
Nov	0	4	5	3	5	14	9	3
Dec	0	1	1	2	5	3	2	
TOTAL		53	36	50	61	153	91	60
Translational		43	11	33	56	138	69	47
Intervention		10	25	17	5	15	22	13

