

INTRODUCTION

Patient-level risk assessments through accurate survival predictions are important for guiding treatment and for selecting patients for clinical trials. In lymphoma, this is often done using prognostic risk scores such as the international prognostic score (IPS) for Hodgkin lymphoma (HL), although newer more sophisticated models have been shown to outperform the conventional prognostic models. However, development of new models poses challenges, that have not previously been discussed thoroughly in the literature. One problem is the optimal splitting of data in training and validation, to utilize often limited data to the fullest and ensure appropriate validation steps. In this study, we use HL as an example, to illustrate how much data is needed for model development and to investigate when an increased size of the training cohort has no meaningful impact on the predictive performance of the models.

AIM

The aim of this study was to investigate the relationship between the size of a training cohort and the predictive performance for different models.

METHOD

Patients with advanced stage HL in 2006-2010, treated with ABVD or BEACOPP.

We compared four models:
1) IPS-D (Dichotomized)
2) IPS-C (Continuous)
3) A-HIPI
4) Random survival forest (RSF)

To estimate the relationship between predictive performance and sample size, a bootstrap method was applied with varying in-bag sample sizes. The concordance index (C-index) was used to measure performance and the mean out-of-bag C-index for each model and sample size was calculated.

RESULTS

Model Performance

Model — A-HIPI — IPS-C — IPS-D — RSF

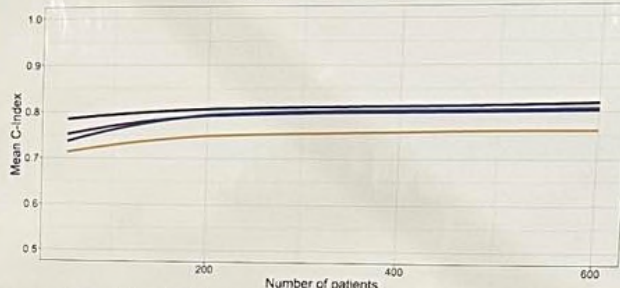


Figure 1. Model performance for the IPS-D, IPS-C, SP-CPI and RSF models for all patients when increasing number of patients in the training cohort.

Model	n patients	C-index
IPS-D	50	0.7
IPS-C	50	0.71
A-HIPI	50	0.72
RSF	50	0.75

Model	n patients	C-index
IPS-D	250	0.74
IPS-C	250	0.79
A-HIPI	250	0.79
RSF	250	0.82

Table 1. Model performance for the IPS-D, SP-CPI and RSF models for all patients with increasing number of patients in the training cohort.

CONCLUSIONS

- 1) Performance plateaus around 150-250 patients, after which more training data yields little to no gain.
- 2) The RSF outperformed the other models at small sample sizes and achieved little gain by increasing sample size.
- 3) This study provides insight into the data requirements for developing prediction models for HL with the possibility of extension to other lymphoma types.
- 4) Potentially improving validation by avoiding an oversized training cohort, leaving more data for validation.

CONTACT INFORMATION

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RESEARCH | FUNDING | SCIENTIFIC OUTPUT

Annual Report 2023

Department of Haematology



AALBORG UNIVERSITY
DENMARK



AALBORG UNIVERSITY HOSPITAL



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1 Research strategy

The Haematology Research Section is an integrated part of Department of Haematology at Aalborg University Hospital. In accordance with the overall research strategy and the Danish Health Act, the clinical practice is based on evidence and development in relation to new diagnostics, therapy and follow up.

Mission

Our mission is to ensure optimal diagnostics, treatment, and care for patients with haematological diseases in the North Denmark Region and furthermore to create a good working environment making Department of Haematology an attractive and inspiring place to work.

Vision and goals

We aim to

- Understand the mechanisms behind disease pathogenesis and resistance of blood diseases (personalised medicine and tumour cell biology)
- Develop preclinical models, methods, and tools for assignment of individual drug resistance of haematological cancer (personalised medicine and tumour cell biology)
- Generate clinical evidence by relevant end points, before implementation and prospective validation of new diagnostics
- Develop biostatistical models and bioinformatic tools to explain haematological diseases and their course of treatment
- Understand the relation between venous thromboses and cancer diseases and develop algorithms to identify patients at risk (thrombosis prophylaxis)
- Monitor the development in diagnostics, treatment, and survival of haematological diseases and their complications by means of cancer epidemiological research methods
- Explore the spatial distribution of haematological cancers in Denmark to identify hotspots for further studies on environmental risk factors
- Develop new and less resource demanding methods for follow-up of patients treated for blood diseases (nurse-led research)
- Be an attractive partner for the pharmaceutical industry regarding industry-initiated clinical trials so that new and experimental treatments may be developed and offered to patients with haematological diseases
- Implement and run investigator-initiated clinical trials
- Attract researchers and clinicians from other regions and universities
- Inspire and attract students and young scientists to do research in haematology

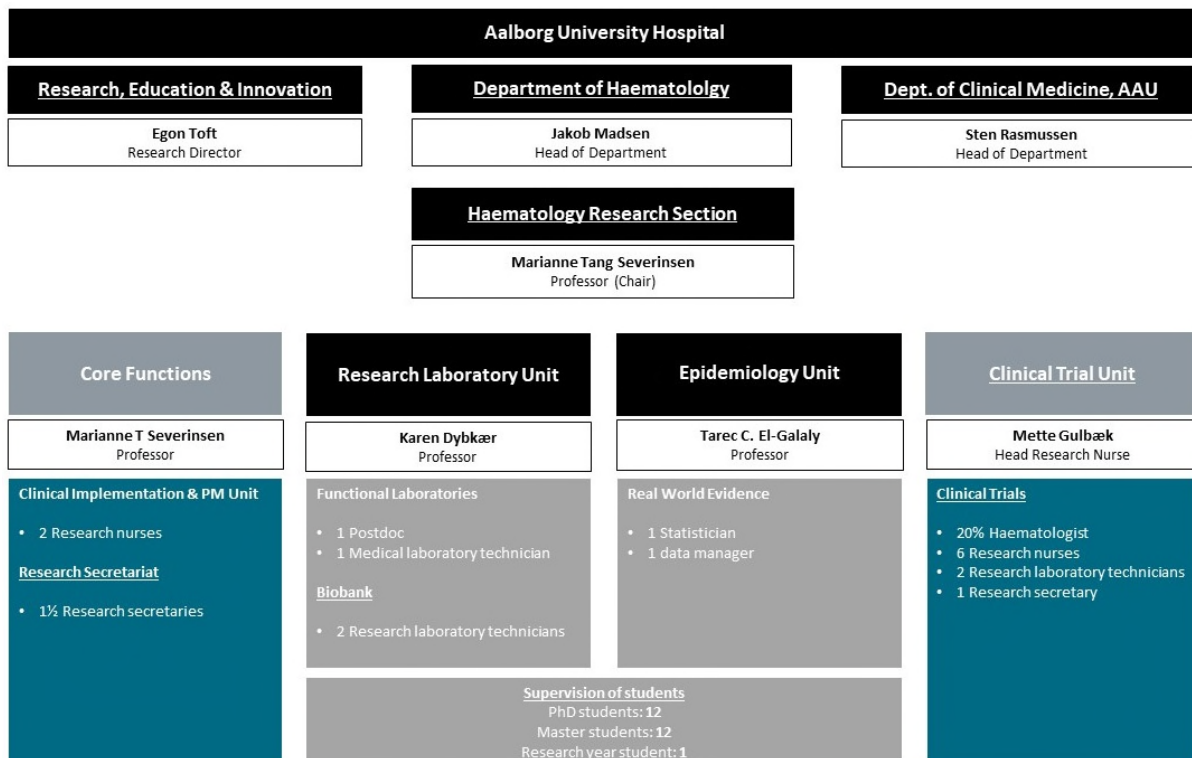


2 Research infrastructures

Organisation

The research section at Department of Haematology, Aalborg University Hospital, was established in 2005, now including clinical research, epidemiology, laboratories, and a secretariat.

Figure 1 | Organisation plan for 2023



December 2023

Professorship responsibilities

Chair professor Marianne Tang Severinsen

We will attain our mission by bridging research and clinical work which is the overarching goal. The research section is organised as a unit within the Department of Haematology. The professor and head of research holds a chair at the faculty/Department of Clinical Medicine and works parttime as a consultant haematologist at the clinical department. Furthermore, the professorship involves being responsible for the education of medical students in the field of haematology. The aim is to engage medical doctors and students to do research, but also to give researchers in other fields an insight into the “real world” seen from a patient-doctor perspective.

Core functions

Clinical Implementation & PM Unit

Clinical Implementation Unit specialises in personalised medicine (PM) and prospective trials.

The Clinical Implementation Unit handles screening, information, and inclusion of trial subjects, obtains informed consent, creates clinical databases, and registers clinical data in the REDCap databases created for the individual projects. In addition, the Clinical Implementation Unit has a coordinating role in relation to collecting biological material, including tissue, blood, and bone marrow samples as well as collecting saliva samples, mouth scrapes and punch biopsies used as normal reference in a PM trial.

The Clinical Implementation Unit collaborates with Department of Molecular Diagnostics and Department of Oncology, Aalborg UH, on personalised medicine as an operational function at Aalborg University Hospital

As for personalised medicine, results from the completed molecular genetic studies are evaluated by specialists and placed in a clinical and literature context and the results are presented and discussed at local tumour conferences (MDTs).

The Clinical Implementation Unit also runs projects including collection and recording of patient-reported outcome data (PRO data).

Haematological Biobank

Bone marrow and peripheral blood samples are registered in the Haematological Biobank under Bio and Genome Bank Denmark (RGBG). The Haematological Biobank collects and stores vital frozen single cell suspensions of mononuclear cells, plasma and serum from patients included in current clinical prospective protocols and health science projects, and from patients suitable for future research projects.

For current clinical prospective protocols and health science projects approved by a regional or national committee on health research ethics, a project-specific research biobank has been set up for the individual projects. For personalised medicine the Haematological Biobank usually also collects, handles, and registers biological tissue in the form of a saliva sample, mouth scrape or skin punch biopsy. For sample handling and processing, detailed standard operating procedures have been developed, ensuring fast and reproducible logistics and freezing.

Biological material from patients with haematological diagnoses is collected and stored in the haematological biobank if informed consent has been given by the patient. The sample material can be used if a future course of treatment requires additional investigations for the individual patient. Sample material can also be used in future research projects if accepted by a committee on health research ethics, given an opportunity for improving diagnostics and treatment methods for future patients is present.

Research Secretariat

Research Secretaries Anne Lindblom & Lise Tordrup Elkjær

The research secretariat coordinates and provides secretarial and administrative assistance to professors, researchers, and students at the research laboratory and epidemiology unit as well as the biobank, and the clinical implementation & PM unit.

The research secretariat performs research-related administrative tasks including

- administration of grants, research accounts and annual accounts
- preparation of budgets incl. monthly updates and financial reports
- administration of staff-related matters incl. recruitment and employment
- booking, administration and coordination of travels and conferences
- organising and taking minutes at meetings
- preparation, coordination, translation, editing, and proofreading of project descriptions, scientific papers, reports, and strategies
- submission of manuscripts for publication, applications for funding, and applications for regulatory authorities
- maintenance of office filing systems and web pages

The research secretariat takes part in a national association of research and project secretaries within oncology and haematology and organised the annual meeting which was held in Aalborg in September 2023.

Haematological Research Laboratory Unit

Professor Karen Dybkær

The Haematological Research Laboratory Unit has focus on molecular analyses of haematological cancers and how to use these in combination with clinical information to identify new determinants and mechanisms that affect disease development, sensitivity to therapeutic drugs as well as disease classifications. Based on genome editing with CRISPR-Cas9 technology spanning over genome analyses, functional analyses, biobanking, and participation in prospective clinical trials, we strive towards better treatment and risk stratification of cancer patients. The projects are all based on interdisciplinarity and collaboration with local, national, and international partners. The unit works in an innovative and inspiring research environment from which many PhD, master and bachelor students have already graduated.



Epidemiology & Real-World Evidence Unit

Professor Tarek C El-Galaly

The Epidemiology & Real-World Evidence Unit has focus on conducting high-quality and practice-changing studies in haematology using local, nationwide, or international real-world data. Strong international collaborations and core functions in national and international studies characterise this group. The group is highly experienced in conducting clinical research and implementation of results. The areas of strength, all documented by high impact publications and international collaborations, are dynamic prognostic model development, implementation of decision support tools, survival statistics, real-world effectiveness of treatment interventions, efficient diagnostic work-up and disease surveillance in haematology and late toxicities. The group is multi-disciplinary with physicians and statisticians working closely together on research with clinical impact.

Clinical Trial Unit

Manager, Head Research Nurse Mette Gulbæk & Project Secretary Elisabeth Vilsbæk Flensted

The Clinical Trial Unit (CTU) at the Department of Haematology supports clinical research activity within the department. The unit continuously participates in clinical trials for the large haematological diseases and thereby contributes to gather new knowledge and to improve the quality of patient treatment. A large part of the activity concerns worldwide industry-initiated trials and the unit has experience with a large portfolio of studies spanning from phase 1A studies to phase 4 studies. In practice this means that the staff are already familiar with new patient treatments once they are approved for treatment, thus giving the department a priceless lead and ensuring a high-quality standard.

Our general CTU activities include screening of patients for inclusion in clinical protocols, administration of study drugs, a guarantee of high data quality, registration of data in project databases, and compliance with protocols and legislation. In March 2023 our CTU attended a sponsor audit as a high recruitment site in a trial of CLL patients and the outcome of the audit was most satisfactory. We delivered quality data to sponsor and there were only four minor findings. Furthermore, our CTU was the first and only including site in an ALL trial.

Another important function of the CTU is participation in investigator-initiated studies, partly studies initiated from other departments and researchers in Denmark and partly local investigator-initiated studies. Consequently, the CTU has in recent years built up solid experience as sponsor, conducting clinical trials locally, nationally, and internationally with preparation of study protocols, applications to regulatory authorities, design of case report forms (CRFs) for registration of study data, and other sponsor responsibilities. Additionally, the CTU facilitates the conduct of other types of studies such as questionnaire studies and register studies as well as collection of biological samples, thus supporting studies originating from other units of the haematology research section.

3 Research projects

Clinical studies

Investigator-initiated clinical studies, conducted by the clinical implementation unit or as part of PhD projects, and industry-initiated clinical trials, conducted by the clinical trial unit, are listed below in alphabetical order. They are identified by approval ID from a regulatory authority such as CTIS/Eu-draCT (clinical trials), the Danish National Committee on Health Research Ethics (NVK), a local research ethics committee or a regional record of processing activities cf. GDPR Art. 30.

Table 1

Study Title	Principal Investigator (PI)	Approval ID
AmbuFlex - Individualised patient follow-up	Jakob Madsen , MD, Department Medical Director, Department of Haematology, Aalborg UH	Not applicable; quality control project
BosuPeg - A study of efficacy and safety of long-acting low dose ropeginterferon in patients with chronic myeloid leukemia treated with bosutinib from diagnosis: a randomized prospective trial	Henrik Hjorth-Hansen, Department of Haematology, St. Olav's Hospital Trondheim, Norway. National PI DK: Andreja Dimitrijevic, Department of Haematology Odense University Hospital, Odense Local PI: Rie Sander Bech , Senior Registrar, Department of Haematology, Aalborg University Hospital	S-20190041
CircRNA - Identifikation af molekylære mekanismer under udvikling af resistens mod Revlimid i myelomatose	Lasse Sommer Kristensen, Associate Professor, Institute for Biomedicine, Aarhus University Local PI: Karen Dybkær , Professor PhD and Henrik Gregersen Professor, MD, PhD, Department of Haematology, Aalborg University Hospital	1-10-72-170-21
Cured but not well - Haematological cancer survivors' experiences of chemotherapy-induced peripheral neuropathy in everyday life: a phenomenological-hermeneutic study.	Mette Louise Roed , MSc in Health Science, Department of Haematology, Aalborg University Hospital	F2023-105
DELPHI - Danish Elderly Lymphoma Patient Hematopoietic Investigation	Kirsten Grønbaek, Professor, MD, DMSc, Department of Haematology, Rigshospitalet, Copenhagen Local PI: Tarec C. El-Galaly , Professor, MD, DMSc, Department of Haematology, Aalborg UH	H-20077410
EVI-3 - A multicenter, randomized, parallel-group, placebo-controlled phase II study of the efficacy and safety of oral vitamin C supplement in combination with azacitidine in higher-risk MDS, CMML, and low blast-count AML	Kirsten Grønbaek, Professor, MD, DMSc, Department of Haematology, Rigshospitalet, Copenhagen. Local PI: Marianne Tang Severinsen, Professor, MD, PhD, Department of Haematology, Aalborg UH	H-18040929

Study Title	Principal Investigator (PI)	Approval ID
Excaliber - A Phase 3, Randomized, Multicenter, Open-label Study Comparing Iber-domide, Daratumumab and Dexamethasone (IberDd) versus Daratumumab, Bortezomib, and Dexamethasone (DvD) in Subjects with Relapsed or Refractory Multiple Myeloma	Sponsor: Celgene Corporation Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-000431-49
GC-MDS-AML - Gastrointestinal complication in Patients with Myelodysplastic Syndrome or Acute Myeloid Leukemia undergoing Treatment with 5-Azacitidin - A clinical follow-up study of patients with haematological malignancies treated with 5-Azacitidin.	Sponsor: Christina Brock, Professor, DVM, PhD, Mech-Sense, Aalborg UH PI: Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg UH	N-20210017
GCT3013-03 - Phase 1b/2, Open-Label, Safety and Efficacy Study of Epcoritamab (GEN3013; DuoBody®-CD3xCD20) in Relapsed/Refractory Chronic Lymphocytic Leukemia and Richter's Syndrome	Sponsor: Genmab A/S Local PI: Thor Høyer , Senior Registrar, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-000848-57
GCT3013-05 - A Randomized, Open-Label, Phase 3 Trial of Epcoritamab vs Investigator's Choice Chemotherapy in Relapsed/Refractory Diffuse Large B-cell Lymphoma	Sponsor: Genmab A/S Local PI: Paw Jensen , Consultant, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-003016-27
GCT3014-01 - An Open-Label, Multicenter, Phase 1/2 Trial of GEN3014 (HexaBody®-CD38) in Relapsed or Refractory Multiple Myeloma and Other Hematologic Malignancies	Sponsor: Genmab A/S Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-003781-40
GenKabCell - Genetic characterisation of B-cell neoplasia	Charlotte G. Nyvold, Professor, MSc, PhD, Department of Haematology, Odense University Hospital Local PI: Karen Dybkær , professor, MSc, PhD, and Marianne Tang Severinsen, Professor, MD, PhD, Department of Haematology, Aalborg UH	S-20160069
Golden Gate - Phase 3 Randomized, Controlled Study of Blinatumomab Alternating with Low-intensity Chemotherapy Versus Standard of Care for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia with Safety Run-in	Sponsor: Amgen Local PI: Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-004498-29
hMN - Identifikation og funktionel betydning af medfødte genetiske varianter der prædisponerer til myeloid neoplasia hos voksne i Danmark	Kirsten Grønbæk, Professor, MD, DMSc, Department of Haematology, Rigshospitalet, Copenhagen. Local PI: Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg UH	2104062 (NVK ¹)

¹ The Danish National Committee on Health Research Ethics (National Videnskabsetisk Komite)

Study Title	Principal Investigator (PI)	Approval ID
InMind - A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Tafasitamab Plus Lenalidomide in Addition to Rituximab Versus Lenalidomide in Addition to Rituximab in Patients With Relapsed/Refractory (R/R) Follicular Lymphoma Grade 1 to 3a or R/R Marginal Zone Lymphoma	Sponsor: Incyte Corporation Local PI: Paw Jensen , Consultant, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-004407-13
Limber 313 - A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Combination of PI3K δ Inhibitor Parsaclisib and Ruxolitinib in Participants with Myelofibrosis	Sponsor: Incyte Corporation Local PI: Gitte Thomsen , Consultant, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-003130-21
LD-VenEx - Phase II Study of Azacitidine in Combination with Low Dose Intensity Venetoclax in Patients with Acute Myeloid Leukemia With integration of Explorative Multi-Omics and ex vivo Drug Screening Data	Kim Theilgaard-Mönch, MD, DMSc, Department of Haematology, Rigshospitalet, University of Copenhagen Local PI: Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-005461-14
MajesTEC-3 - A Phase 3 Randomized Study Comparing Teclistamab in Combination with Daratumumab SC (Tec-Dara) versus Daratumumab SC, Pomalidomide, and Dexamethasone (DPd) or Daratumumab SC, Bortezomib, and Dexamethasone (DvD) in Participants with Relapsed or Refractory Multiple Myeloma	Sponsor: Janssen-Cilag A/S Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-004742-11
MajesTEC-9 - A Phase 3 Randomized Study Comparing Teclistamab Monotherapy versus Pomalidomide, Bortezomib, Dexamethasone (PvD) or Carfilzomib, Dexamethasone (Kd) in Participants with Relapsed or Refractory Multiple Myeloma who have Received 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Monoclonal Antibody and Lenalidomide	Sponsor: Janssen-Cilag A/S Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2022-000928-37
MICRO - Methylphenidat, double-blind, placebo-controlled CROss-over trial	Henrik Frederiksen, Consultant, MD, PhD, Odense University Hospital Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	S-20170101
MK1026-003 - A Phase 2 Study to Evaluate the Efficacy and Safety of MK-1026 in Participants with Hematologic Malignancies	Sponsor: MSD Danmark Aps Local PI: Thor Høyer , Senior Registrar, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-002324-36
MK1026-008 - A Phase 2 Study to Evaluate the Efficacy and Safety of MK-1026 in Participants with Hematologic Malignancies	Sponsor: MSD Danmark Aps Local PI: Thor Høyer , Senior Registrar, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2022-500164-35-00
NIPA - Non-invasive Diagnosis of Invasive Pulmonary Aspergillosis by use of Biomarkers in Exhaled Breath Condensate	Inger Lise Gade , MD, PhD, Registrar, Department of Haematology, Aalborg University Hospital, Department of Haematology, Aarhus University Hospital	N-20190070

Study Title	Principal Investigator (PI)	Approval ID
NGAM12 - Double-blind, Randomized, Placebo-controlled, Prospective Phase III Study Evaluating Efficacy and Safety of Panzyga in Primary Infection Prophylaxis in Patients with Chronic Lymphocytic Leukemia ("PRO-SID" study)	Sponsor: Octapharma Pharmazeutika Local PI: Thor Høyer, Senior Registrar, MD, Department of Haematology, Aalborg UH	EudraCT No. 2019-004375-40
NOVIT-1 - Early detection and prevention of Neuropathy and Cognitive Impairment following treatment for Haematological Malignancies	Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg UH	N-20190068
PE-EBC - Non-invasive Diagnosis of Pulmonary Embolism by use of Biomarkers in Exhaled Breath Condensate	Inger Lise Gade , MD, PhD, Registrar, Department of Haematology, Aalborg University Hospital, Department of Haematology, Aarhus University Hospital	N-20180086
POLAR BEAR - R-MINI-CHOP versus R-MINI-CHP in combination with polatuzumab-vedotin, as primary treatment for patients with diffuse large B-cell lymphoma, ≥80 years, or frail ≥75 years – an open label randomized Nordic Lymphoma Group phase III trial - NLG-LBC7	Sponsor: Nordic Lymphoma Group. Coordinating PI: Mats Jerkeman, Lund University Hospital, Lund, Sweden. Local PI: Jakob Madsen, Department Medical Director, Department of Haematology, Aalborg University Hospital.	H-20028621
PRO-B-HMA - Quality-of-life and treatment effect associated with the use of DNA hypomethylating drugs in the treatment of myelodysplastic syndrome, chronic myelomonocytic leukaemia and acute myeloid leukaemia – a Danish nationwide study	Christen Lykkegaard Andersen and Professor, DMSc, Chief Consultant, Haematologist Kirsten Grønbæk Local PI: Marianne Tang Severinsen, Professor, MD, PhD, Department of Haematology, Aalborg UH	H-20032246
ProSeq Cancer (Haematology) <i>En prospektiv undersøgelse af omfattende genomiske analyser hos patienter med uhelbredelig kræft, med henblik på målrettet behandling</i>	Morten Ladekarl, Professor, MD, PhD, Department of Oncology, Aalborg UH Local PI: Marianne Tang Severinsen, Professor, MD, PhD, Department of Haematology, Aalborg UH	N-20200018
PTH - Targeted treatment of patients with haematological diseases	Kirsten Grønbæk, Professor, MD, DMSc, Department of Haematology, Rigshospitalet, Copenhagen. Local PIs: Marianne Tang Severinsen, Professor, MD, PhD, Department of Haematology, Aalborg UH, Anne Roug, Clinical Associate Professor, MD, PhD, Department of Clinical Medicine, Aalborg University; Karen Dybkær, Professor, MSc, PhD, Department of Haematology, Aalborg UH; Martin Bøgsted, Professor, MSc, PhD, Department of Haematology, Aalborg UH	1705391 (NVK)
RetroGen - Retrospektiv analyse af kemoterapi-specifik molekylær resistens ved hæmatologiske kræftsygdomme - multiparametriske undersøgelser af arkiveret væv og blod registreret i klinisk biobankdatabase 1990-2022	Karen Dybkær , Professor, MSc, PhD, Department of Haematology, Aalborg UH	N-20140099

Study Title	Principal Investigator (PI)	Approval ID
RetroSeq - Retrospektiv gensekventering og personlig medicin - Afprøvning af ny in vitro gendiagnostik omfattende gensekventering af humant væv med henblik på klinisk validering af personlig medicin-konceptet.	Karen Dybkær , Professor, MSc, PhD, Department of Haematology, Aalborg UH	1706295 (NVK)
SABLe - Selinexor with alternating bortezomib or lenalidomide plus dexamethasone in transplant ineligible newly diagnosed multiple myeloma patients	Ida Bruun Kristensen, MD, Odense University Hospital, Department of Haematology on behalf of Nordic Myeloma Study Group Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	EudraCT No.: 2020-006060-89
SGN35-031 - A Randomized, Double-blind, Placebo-Controlled, Active-Comparator, Multi-center, Phase 3 Study of Brentuximab Vedotin or Placebo in Combination with Lenalidomide and Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-cell Lymphoma	Sponsor: Seagen Inc. Local PI: Jakob Madsen , Department Medical Director, Department of Haematology, Aalborg University Hospital.	EudraCT No.: 2020-002686-33
Skyglo - A phase III, multicenter, randomized, openlabel study comparing the efficacy and safety of Glofitamab (RO7082859) in combination with polatuzumab vedotin plus rituximab, cyclophosphamide, doxorubicin, and prednisone (polarchp) versus polarchp in patients with large b-cell lymphoma.	Sponsor: Roche Pharmaceuticals a/s Local PI: Paw Jensen , Consultant, MD, Department of Haematology, Aalborg UH	EudraCT No.: 2023-504028-24-00
Transform2 - A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination with Ruxolitinib Versus Best Available Therapy in Subjects with Relapsed/Refractory Myelofibrosis	Sponsor: ABBVIE A/S Local PIs: Marianne Tang Severinsen , Professor, MD, PhD, Department of Haematology, Aalborg	EudraCT No. 2020-000557-27
Vertebroplasty - Palliative treatment of multiple myeloma patients with painful vertebral lesions. A multicenter randomized controlled trial of vertebroplasty in addition to usual treatment	Professor Niels Abildgaard, Head of Research, Hematology Pathology Research Laboratory, Department of Hematology, Odense University Hospital. Local PI: Henrik Gregersen , Consultant, MD, PhD, Department of Haematology, Aalborg UH	S-20200075

Supervision and student projects

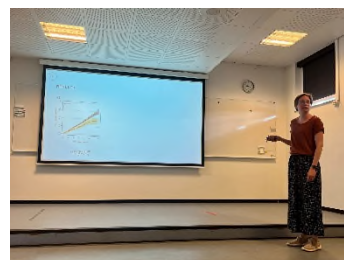
Ongoing PhD projects

Eva Futtrup Maksten, MD, Department of Haematology

Title: *Long-term complications following treatment for haematological malignancies: Neuropathy and Cognitive Impairment*

Enrolment: 1 January 2020

Supervisor: Marianne Tang Severinsen. Co-supervisors: Lasse Hjort Jakobsen, Tarec C. El-Galaly, Kristian Hay Kragholm (Department of Cardiology)



Joachim Bæch, MD, Department of Haematology

Title: *Late toxicities of steroid-including immunochemotherapy regimens for patients with lymphoma*

Enrolment: 1 May 2020

Supervisor: Tarec C. El-Galaly. Co-supervisors: Lasse Hjort Jakobsen, Henrik Frederiksen (Department of Haematology OUH), Marianne Tang Severinsen



Issa Ismail Issa, MSc in Biomedicine, Department of Clinical Medicine, Aalborg University

Title: *Targeting multidrug resistance mechanisms in Diffuse Large B-cell Lymphoma*

Enrolment: 1 October 2020

Supervisor: Karen Dybkær. Co-supervisor: Martin Bøgsted



Lars Børtly Nielsen, MSc in Economics, CLINDA – Center for Clinical Data Science, Aalborg University

Title: *Application of individual-based registrations of systemic anti-cancer therapy for monitoring expenditures and access to treatment*

Enrolment: 1 January 2021

Supervisor: Rasmus Brøndum. Co-supervisors: Martin Bøgsted, Marianne Tang Severinsen

Ahmed Ludvigsen Al-Mashhadi, MD, Department of Haematology

Title: *Outcomes of rare lymphomas*

Enrolment: 1 September 2021

Supervisor: Tarec C. El-Galaly. Co-supervisor: Lasse Hjort Jakobsen, Thomas Stauffer Larsen (Syddansk Universitet)

Daniel Kristensen, MD, Department of Haematology

Title: *REFORM-AML: A nationwide retrospective study of population-based acute myeloid leukemia tumor genetic data*

Enrolment: 1 October 2021

Supervisor: Anne Stidsholt Roug. Co-supervisors: Martin Bøgsted, Marianne Tang Severinsen, Rasmus Froberg Brøndum

Rasmus Rask Kragh Jørgensen, MSc in Operations Research, Department of Haematology

Title: *Advanced statistical methods for studies of lymphoma prognosis and treatment outcomes in a real-world setting*

Enrolment: 15 November 2021

Supervisor: Lasse Hjort Jakobsen. Co-supervisors: Tarec Christoffer El-Galaly, Andreas Kiesbye Øvlisen, Marianne Tang Severinsen, Sandra Eloranta (Karolinska Institutet)

Maja Zimmer Jakobsen, MSc in Health Science and Technology, BSc in nursing, Department of Haematology

Title: *Multidisciplinary investigation of proteasome inhibitor response in multiple myeloma*

Enrolment: 1 November 2022

Supervisor: Karen Dybkær. Co-supervisors: Henrik Gregersen, Rasmus Froberg Brøndum

Maren Poulsen Jørgensen, MD, Department of Haematology

Title: *Socioeconomic impact, comorbidities and long-term outcomes related to mastocytosis and the treatment thereof*

Enrolment: 1 January 2023

Supervisor: Marianne Tang Severinsen. Co-Supervisors: Tarec C. El-Galaly, Andreas Kiesbye Øvlisen

Hulda Haraldsdóttir, MSc in Health Science and Technology, Department of Haematology

Title: *The role of DNA Damage Repair in selected cancers*

Enrolment: 1 January 2023

Supervisor: Karen Dybkær. Co-Supervisors: Inge Søkilde Pedersen og Rasmus Froberg Brøndum

Lisa-Maj Christensen, MD, Department of Haematology

Title: *Characteristics, treatment and survival in patients with mixed phenotype acute leukemia*

Enrolment: 1 January 2023

Supervisor: Marianne Tang Severinsen. Co-Supervisors: Karen Dybkær, Tarec C. El-Galaly, Kirsten Grønbek.

Mette Hyllegaard Madsen, MD, Department of Occupational and Environmental Medicine and Department of Haematology

Title: *Environmental exposures and risk of hematologic cancers*

Enrolment: 1 August 2023

Supervisor: Jakob Hjort Bønløkke. Co-Supervisors: Marianne Tang Severinsen, Else Toft Würtz og Jörg Schullehner

Mikkel Runason Simonsen, statistician, Department of Mathematical Sciences, AAU, and Department of Haematology

Title: *Improving the clinical utility of prognostic tools through calibration*

Enrolment: 1 November 2023

Supervisor: Rasmus Waagepetersen. Co-Supervisors: Lasse Hjort Jakobsen, Tarec C. El-Galaly

Master student and research year student projects

Christian Teglgaard, Research Year Student, Department of Haematology

Title: *Geographical distribution of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) in Denmark: a national cross-sectional study*

Supervisor: Marianne Tang Severinsen. Co-supervisor: Martin Bøgsted.

Christian Teglgaard, Medical Student, Department of Haematology

Title: *Cardiovascular diseases after high dose chemotherapy and allogeneic stem cell transplant for acute leukemia: A Danish population-based study*

Supervisor: Marianne Tang Severinsen

Asta Brogaard Christensen, BSc, Master Student

Title: *Applying the CRISPR activation system for functional studies of treatment resistance in diffuse large B-cell lymphoma*

Supervisor: Karen Dybkær. Co-supervisors: Hanne Due, Issa Ismail Issa

Cathrine Sylvester, BSc, Master Student

Title: *Unravelling the role of the UBE2A gene, identified in genome-wide CRISPR screens, on treatment response in DLBCL*

Supervisor: Karen Dybkær. Co-supervisors: Maja Zimmer Jacobsen, Hulda Haraldsdóttir

Mette Louise Roed, BSc in nursing, Master Student

Title: *A phenomenological-hermeneutic study of hematological patients' experiences of chemotherapy-induced peripheral neuropathy and its impact on everyday life after a hematological cancer disease*

Supervisors: Kirsten Frederiksen, Helle Enggaard, Marianne Tang Severinsen

Nanna Nørtoft Nielsen, Medical Student

Title: *Second primary malignancies following intensive treatment for adult acute leukemia: A Danish population-based cohort study*

Supervisors: Marianne Tang Severinsen, Daniel Tuyet Kristensen

Rathiba Sivarooban, Medical Student

Title: *Infection Risk Before and After Diagnosis of Angioimmunoblastic T-Cell Lymphoma*

Supervisor: Tarec Christoffer El-Galaly

Simone Brommann og Linea Pilgaard, BSc, Master Students

Title: *Real world data on use of azacitadine in the treatment of patients with high-risk myelodysplastic syndromes in the period 2010-2022.*

Supervisors: Anne Estrup Olesen, Marianne Tang Severinsen



4 Research grants and awards

Major research project grants awarded in 2023

Multidisciplinary investigation of genetic variants in DNA damage repair genes in diffuse large B-cell lymphoma

Professor Karen Dybkær was awarded a grant of 2.37 million DKK from the Danish Cancer Society (KBVU-BK) originating from a donation from *Fabrikant Vilhelm Pedersen og Hustrus Legat*.

Improving Outcomes of Lymphoma-Associated Hemophagocytosis Syndrome Through a Nationwide, Multidisciplinary Research Program

Independent Research Fund Denmark allocated 2.06 million DKK to **Professor Tarec Christoffer El-Galaly** for a Research Project 1.

Genetic variants in predisposition and development of treatment resistant diffuse large B-cell lymphoma

Novo Nordisk Foundation allocated a project grant in the programme 'Clinical and Translational Medicine' to **Professor Karen Dybkær**. This grant amounts to 1.99 million DKK.

Improving the clinical utility of prognostic tools through calibration

For the second time since the launch in 2022 a student from Department of Haematology was awarded a three-year PhD Fellowship from the Danish Data Science Academy (DDSA). This time **PhD Student Mikkel Runason Simonsen**, who is enrolled at the PhD School at Department of Mathematical Sciences, Aalborg University and part-time employed at Department of Haematology, was awarded a PhD Fellowship of 1.89 million DKK to conduct his PhD project.

Follicular Lymphoma - a model disease for patient trajectories, impact of treatment sequence, and patient preferences in chronic cancers

Professor Tarec Christoffer El-Galaly was awarded a grant of 1.77 million DKK from the Danish Cancer Society (KBVU-MS).

Improved genomic characterization of Mixed Phenotype Acute Leukemia optimizing diagnostic and treatment options; a multidisciplinary research program

Professor Marianne Tang Severinsen received a grant of 1.7 million DKK from Danish Cancer Society's 'Knæk Cancer' pool.

External funding 2023

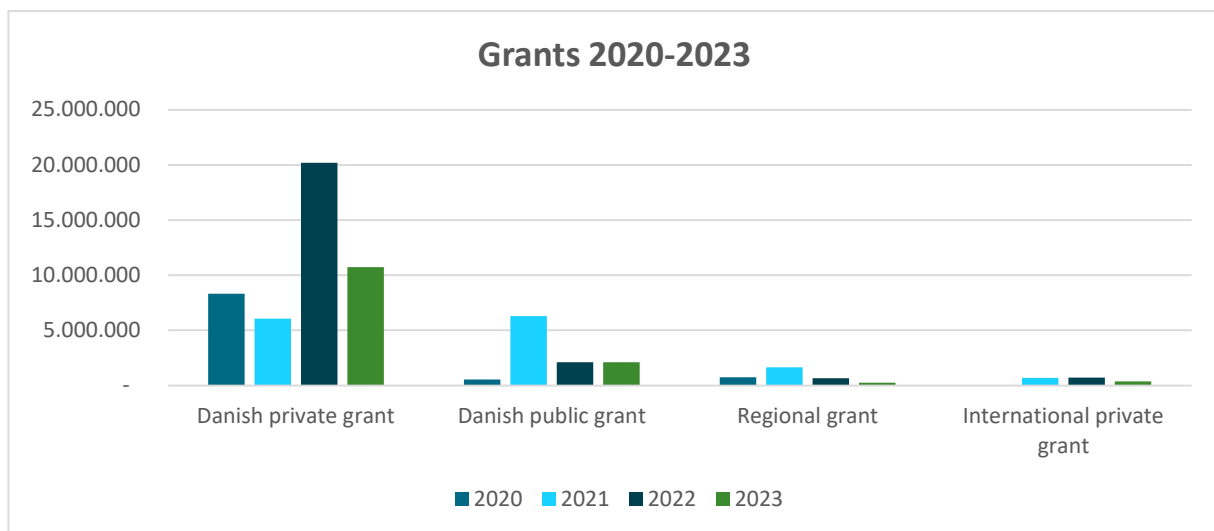
In 2023 the Research Section of Department of Haematology at Aalborg University Hospital sent 64 funding applications resulting in 29 grants amounting to 13.5 million DKK from Danish and international private and public foundations. In 2022, secured funding amounted to 23.7 million DKK. Below is an overview of funders and the projects receiving grants in 2023.

Table 2 | Funding secured in 2023

Funder	Project	Recipient	Type	Duration
A.P. Møller Fonden til Lægevidenskabens Fremme	Travel Grant	Eva F. Maksten	Danish private grant	2023
Acute Leukaemia Group (ALG)	PhD: MPAL	Lisa-Maj Christensen	Danish private grant	2023-2025
Danish Cancer Society	Travel Grant	Hanne Due	Danish private grant	2023
Danish Cancer Society	Travel Grant	Issa Ismail Issa	Danish private grant	2023
Danish Cancer Society (Knæk Cancer)	PhD: MPAL	Marianne T. Severinsen	Danish private grant	2024-2026
Danish Cancer Society KBVU-BK Project	PhD: LAHS	Tarec El-Galaly	Danish private grant	2024-2026
Danish Cancer Society KBVU-BK Project	DDR-DLBCL	Karen dybkær	Danish private grant	2024-2026
Danish Cancer Society KBVU-MS Project	PhD: FL	Tarec El-Galaly	Danish private grant	2024-2026
Danish Data Science Academy (DDSA)	PhD Fellowship	Mikkel R. Simonsen	Danish private grant	2023-2026
Danish Lymphoma Group (DLG), Young Scientists	HL-pulm.	Julie H. Vandtved	Danish private grant	2023
Danish Lymphoma Group (DLG), Young Scientists	HDT-inf..	Freja T. Severinsen	Danish private grant	2023
Grosserer L.F. Foghts Fond	CRISPR	Issa Ismail Issa	Danish private grant	2023
Grosserer Vald. Foersom og hustru Thyra Foersom født Otto's Fond	CRISPR	Issa Ismail Issa	Danish private grant	2023
Heinrich Kopps' Grant	Acute Leukaemia	Daniel Kristensen	Danish private grant	2024
Novo Nordisk Foundation, Project Grants in Clinical and Translational Medicine	DDR-DLBCL	Karen Dybkær	Danish private grant	2024-2026
Simon Spies Fonden	PhD: MM	Maja Zimmer Jakobsen	Danish private grant	2023-2025
Svend Andersen Fonden - scholarship for medical students (AAU)	Acute Leukaemia	Marianne T. Severinsen	Danish private grant	2024
Independent Research Fund Denmark, Research Project 1	PhD: LAHS	Tarec El-Galaly	Danish public grant	2024-2028
Aalborg University - Research Student Grant	Research Student Grant	Nanna Nørtoft	Danish public grant	2023
Aalborg University - Research Student Grant	Research Student Grant	Rathiba Sivaroooban	Danish public grant	2023

Funder	Project	Recipient	Type	Duration
Aalborg University - Research Student Grant	Research Student Grant	Christian Teglgaard	Danish public grant	2023
Aalborg University Doctoral School	Travel Grant	Rasmus R. K. Jørgensen	Danish public grant	2023
Aalborg University Doctoral School	Travel Grant	Eva F. Maksten	Danish public grant	2023
Nordic Cancer Union (NCU)	RWD	Tarec El-Galaly	International private grant	2024
Health Hub - Founded by Spar Nord Fonden	Ketone Project	Inger Lise Gade	Regional grant	2024
North Denmark Region Innovation Pool	Ketone Project	Inger Lise Gade	Regional grant	2023-
Region Nordjyllands Sundhedsvidenskabelige Forskningsfond	PhD	Eva F. Maksten	Regional grant	2023
Reservelægefonden	Travel Grant	Daniel Kristensen	Regional grant	2023
Reservelægefonden	Travel Grant	Daniel Kristensen	Regional grant	2023
Reservelægefonden	Travel Grant	Lisa-Maj Christensen	Regional grant	2023

Figure 2 | Breakdown of types of research grants awarded in 2020 – 2023



5 Dissemination of scientific output

Research stays abroad

PhD Student Eva Futtrup Maksten, research stay in Tromsø, Norway, 12 February – 22 April

PhD Student Rasmus Rask Jørgensen, research visit at Karolinska, Stockholm, Sweden, 19 – 24 March, and research stay in New York, USA 10 August – 21 October.

Guest researchers and students from abroad

PhD Student Ian Helstrup Nielsen, Department of Biomedicine, Aarhus University, 4 week research visit, supervised by Professor Karen Dybkær

Collaborations

Mayo Clinic, Rochester, Minnesota, USA

Stanford University, California, USA

Karolinska Universitetet, Stockholm, Sweden

Oslo University, Oslo, Norway

The University of Western Australia, Perth, Western Australia, Australia

The University of British Columbia, Vancouver, British Columbia, Canada

Duke University, Durham, North Carolina, USA

Universitetet i Tromsø, Norges Arktiske Universitet, Tromsø, Norway

University of Nebraska Medical Center, Omaha, Nebraska, USA

National and international society memberships and chairs

Dansk Hæmatologisk Selskab (DHS)

Danish Lymphoma Group (DLG)

Acute Leukemia Group (ALG)

Danish Myeloma Study Group (DMSG)

Danish Study Group for Chronic Myeloid Diseases (DSKMS)

Danish National Genome Center (NGC) Research and Infrastructure Committee

Nordic Lymphoma Group (NLG)

Nordic MDS Group (NMDSG)

Nordic AML Group (NAML)

Medical Research Council UK (MRC)

Nordic Myeloma Study Group (NMSG)

European Myeloma Network (EMN)

Scandinavian Thrombosis and Cancer group (STAC)



6 Scientific output

Bibliometrics

Table 3 | *h*-index of research leaders. Indexed publications, citations, and H-index.

Title	Name	Publications		Citations		H-index	
		Scopus	WoS	Scopus	WoS	Scopus	WoS
Professor	Marianne Tang Severinsen	106	162	2365	2241	24	23
Professor	Karen Dybkær	138	206	4922	4871	36	37
Professor	Tarec Christoffer El-Galaly	139	222	2455	2394	29	28

Data derived from Scopus and Web of Science (WoS).

Not all publications are indexed in Scopus or Web of Science

Figure 3 | Number of publications in subcategories in the past 10 years (2014-2023)

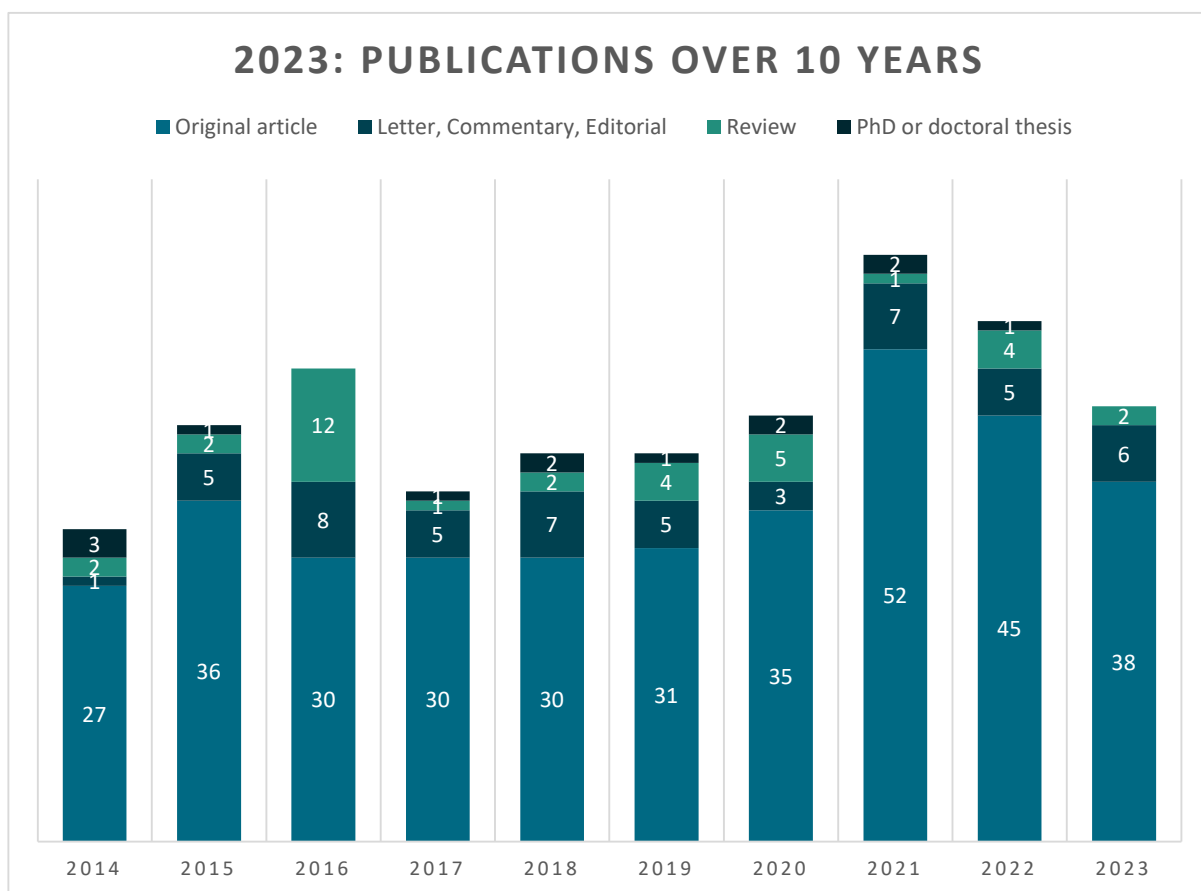
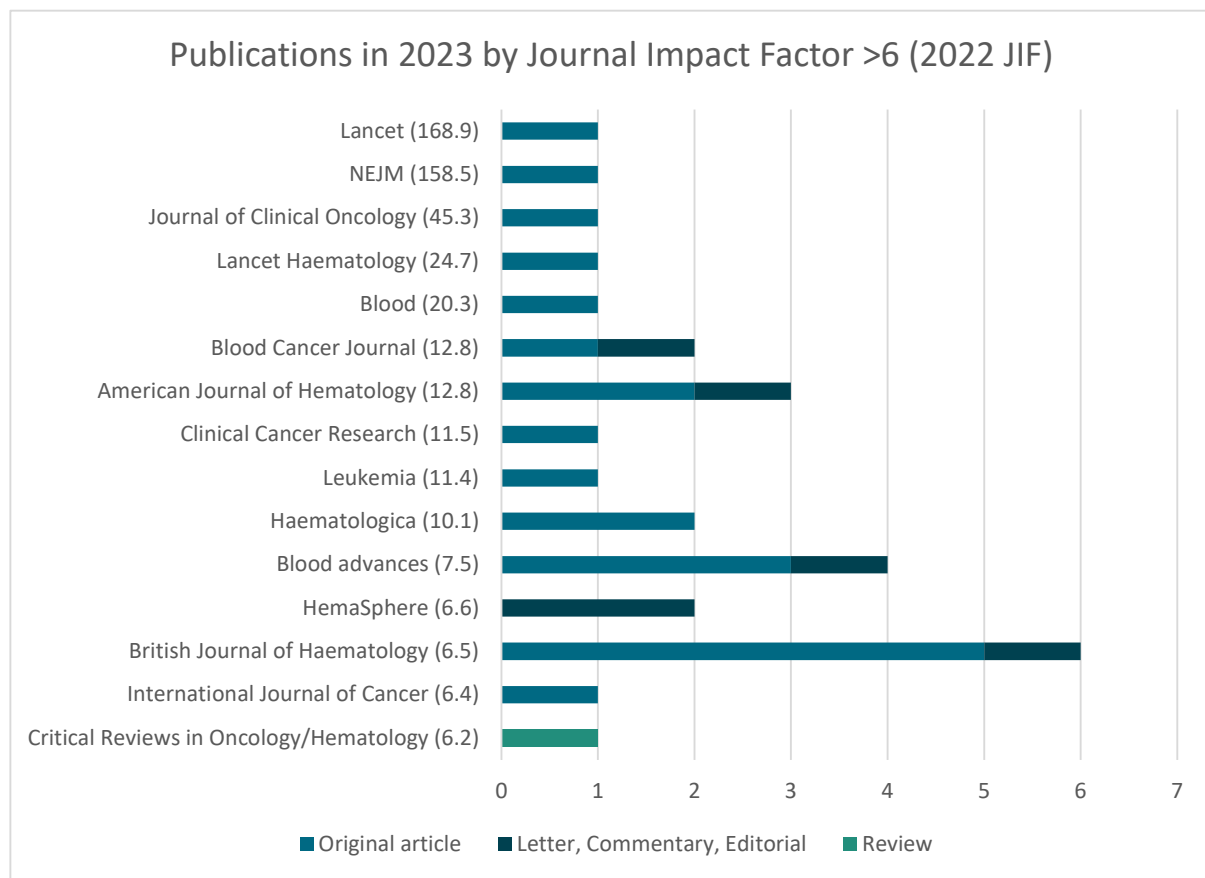


Figure 4 | Papers published in journals with impact factor (IF) >6 (IF given in brackets) 2023



7 Publication list

Publications in 2023

Sorted by journal impact factor

Impact factor >10

1. Verstovsek, S, Gerds, A, Vannucchi, A, Vannucchi, A, Al-Ali, HK, Lavie, D, Kuykendall, AT, Grosicki, S, Iurlo, A, Goh, YT, Lazaroiu, MC, Egyed, M, Fox, ML, McLornan, D, Harrison, CN, Perkins, A, Yoon, SS, Gupta, V, Kiladjan, JJ, Granacher, N, Lee, SE, Ocroteala, L, Passamonti, F, Klencke, BJ, Ro, S, Donahue, R, Kawashima, J, Mesa, R, MOMENTUM Study Investigators & **Severinsen, MT** 2023, 'Momelotinib versus danazol in symptomatic patients with anaemia and myelofibrosis (MOMENTUM): results from an international, double-blind, randomised, controlled, phase 3 study', *The Lancet*, bind 401, nr. 10373, s. 269-280. [https://doi.org/10.1016/S0140-6736\(22\)02036-0](https://doi.org/10.1016/S0140-6736(22)02036-0) (IF 168.9)
2. Eichhorst, B, Niemann, CU, Kater, AP, Fürstenau, M, von Tresckow, J, Zhang, C, Robrecht, S, Gregor, M, Juliusson, G, Thornton, P, Staber, PB, Tadmor, T, Lindström, V, da Cunha-Bang, C, Schneider, C, Poulsen, CB, Illmer, T, Schöttker, B, Nösslinger, T, Janssens, A, Christiansen, I, Baumann, M, Frederiksen, H, van der Klift, M, Jäger, U, Leys, MBL, Hoogenboom, M, Lotfi, K, Hebart, H, Gaska, T, Koene, H, Enggaard, L, Goede, J, Regelink, JC, Widmer, A, Simon, F, De Silva, N, Fink, A-M, Bahlo, J, Fischer, K, Wendtner, C-M, Kreuzer, KA, Ritgen, M, Brüggemann, M, Tausch, E, Levin, M-D, van Oers, M, Geisler, C, Stilgenbauer, S, Hallek, M, German CLL Study Group (GCLLSG), Haemato-Oncology Foundation for Adults in the Netherlands (HOVON), Nordic CLL Study Groups, Swiss Group for Clinical Cancer Research (SAKK), The Israeli CLL Association & Cancer Trials Ireland 2023, 'First-Line Venetoclax Combinations in Chronic Lymphocytic Leukemia', *The New England Journal of Medicine*, bind 388, nr. 19, s. 1739-1754. <https://doi.org/10.1056/NEJMoa2213093> (IF 158.5)
3. Lewis, KL, Jakobsen, LH, Villa, D, Smedby, KE, Savage, KJ, Eyre, TA, Cwynarski, K, Bishton, MJ, Fox, CP, Hawkes, EA, Maurer, MJ, El-Galaly, TC, Cheah, CY, International CNS Prophylaxis Study Group & Øvlisen, AK 2023, 'High-Dose Methotrexate as CNS Prophylaxis in High-Risk Aggressive B-Cell Lymphoma', *Journal of Clinical Oncology*, bind 41, nr. 35, s. 5376-5387. <https://doi.org/10.1200/JCO.23.00365> (IF 45.3)
4. Trab, T, Baech, J, Jakobsen, LH, Husby, S, Severinsen, MT, Eloranta, S, Gørløv, JS, Jørgensen, JM, Gudbrandsdottir, S, Larsen, TS, Brown, P, Grønbaek, K, Smedby, KE & El-Galaly, TC 2023, 'Second primary malignancies in patients with lymphoma in Denmark after high-dose chemotherapy and autologous haematopoietic stem-cell transplantation: a population-based, retrospective cohort study', *The Lancet Haematology*, bind 10, nr. 10, s. e838-e848. [https://doi.org/10.1016/S2352-3026\(23\)00212-0](https://doi.org/10.1016/S2352-3026(23)00212-0) (IF 24.7)
5. Fürstenau, M, Thus, YJ, Robrecht, S, Mellink, CHM, van der Kevie-Kersemaekers, A-MF, Dubois, J, von Tresckow, J, Patz, M, Gregor, M, Thornton, P, Staber, PB, Tadmor, T, Levin, M-D, da Cunha-Bang, C, Schneider, C, Poulsen, CB, Illmer, T, Schöttker, B, Janssens, A, Christiansen, I, Noesslinger, T, Baumann, M, Hebart, H, Gaska, T, Regelink, J, Dompeling, EC, Lindstrom, V, Juliusson, G, Widmer, AA, Goede, JS, Goldschmidt, N, Simon, F, De Silva, N, Fink, AM, Fischer, K, Wendtner, C-M, Ritgen, M, Brüggemann, M, Tausch, E, Spaargaren, M, Eldering, E, Stilgenbauer, S, Niemann, CU, Hallek, M, Eichhorst, B, Kreuzer, K-A & Kater, AP 2023, 'High karyotypic complexity is an independent prognostic factor in patients with CLL treated with venetoclax combinations', *Blood*, bind 142, nr. 5, s. 446-459. <https://doi.org/10.1182/blood.2023019634> (IF 20.3)
6. Ludvigsen Al-Mashhadi, A, Cederleuf, H, Kuhr Jensen, R, Holm Nielsen, T, Bjerregård Pedersen, M, Bech Mortensen, T, Relander, T, Jerkeman, M, Orved Gang, A, Kristensen, AL, Roost Clausen, M, de Nully Brown, P, Tang Severinsen, M, Jakobsen, LH, Ellin, F & El-Galaly, TC 2023, 'Outcome of limited-stage peripheral T-Cell lymphoma after CHOP(-like) therapy: A population based study of 239 patients from the Nordic lymphoma epidemiology group', *American*

- Journal of Hematology*, bind 98, nr. 3, s. 388-397. <https://doi.org/10.1002/ajh.26803> (IF 12.8)
7. Radkiewicz, C, Bruchfeld, JB, Weibull, CE, Jeppesen, ML, Frederiksen, H, Lambe, M, Jakobsen, L, El-Galaly, TC, Smedby, KE & Wåsterlid, T 2023, 'Sex differences in lymphoma incidence and mortality by subtype: a population-based study', *American Journal of Hematology*, bind 98, nr. 1, s. 23-30. <https://doi.org/10.1002/ajh.26744> (IF 12.8)
 8. Wilson, MR, Kirkwood, AA, Wong Doo, N, Soussain, C, Choquet, S, Lees, C, Fox, C, Preston, G, Ahearne, M, Strüßmann, T, Clavert, A, Rusconi, C, Ku, M, Khwaja, J, Narkhede, M, Lewis, K, Durot, E, Smith, J, Renaud, L, Ferreri, AJM, El-Galaly, T, Cwynarski, K, McKay, P & Eyre, TA 2023, 'Dosage of high-dose methotrexate as CNS prophylaxis in DLBCL: A detailed analysis of toxicity and impact on CNS relapse', *American Journal of Hematology*, bind 99, nr. 2, s. E46-E50. <https://doi.org/10.1002/ajh.27167> (IF 12.8)
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 10. Gundesen, MT, Asmussen, JT, Schjesvold, F, Vangsted, AJ, Helleberg, C, Haukås, E, Silkjær, T, Teodorescu, EM, Jensen, BA, Slørdahl, TS, Nahi, H, Waage, A, Abildgaard, N, Lund, T & Nordic Myeloma Study Group 2023, 'Potential value of pre-planned imaging of bone disease in multiple myeloma', *Blood Cancer Journal*, bind 13, 105. <https://doi.org/10.1038/s41408-023-00880-0> (IF 12.8)
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Impact factor 6-9

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