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Indhold

Exceptional Young Scientist Abstract #i-vi

i: Can we kill three birds with one stone? A cluster-randomised, crossover trial offering self-sampling for cervical- and colorectal cancer screening to women attending breast cancer screening

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Abstract
Introduction
The Danish breast cancer (BC) screening programme boasts an 83% participation rate, surpassing cervical (CC) and colorectal cancer (CRC) screening rates of 60% each. Non-participation often stems from logistic challenges rather than a deliberate choice not to participate. This study aims to evaluate the efficacy of offering self-sampling kits to non-participants in CC and CRC screening while they attend BC screening.

Materials and methods
A cluster-randomised, crossover trial was conducted from September 2021 to May 2022, with follow-up until Jan 1st, 2023. On 100 selected days, five Danish BC screening units were randomly allocated in a 1:4 ratio as intervention or control units.
Women attending BC screening at the intervention unit were offered administrative check-up on their CC and CRC screening status, with self-sampling kits offered to those overdue.
Concurrently, a user-perspective questionnaire was distributed to both groups.

Results
A total of 27,116 women were included in the study, with 5,618 and 21,498 in the intervention and control groups, respectively.
At end of follow-up, coverage was significantly higher in the intervention group compared to the control group in CC screening (88.3% vs 83.5%, RD: 4.8 percentage points, 95% CI: 3.6-6.0) and CRC screening (79.8% vs 76.0%, RD: 3.8 percentage points, 95% CI: 2.6-5.1). Among overdue women, 32% participated in CC screening in the intervention group compared to 6.1% in the control group. In CRC screening, 23.8% of overdue women participated in the intervention group compared to 8.9% in the control group.
No difference between the intervention and control groups was detected regarding satisfaction with BC screening, and the intervention was well-received by women in the intervention group.

Conclusions
Offering self-sampling kits to women overdue for CC and CRC screening during BC screening was a feasible intervention that significantly increased participation.

ii Missed cancer in the Danish head and neck cancer fast-track program: Results from a tertiary cancer center

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Abstract
Introduction
The Danish head and neck cancer fast-track program is a national standardized pathway aiming to reduce waiting time and improve survival for patients suspected of cancer in the head and neck (HNC). Until now, the frequency of missed cancer in the fast-track program has not been addressed. A missed cancer leads to treatment delay and may cause disease progression and worsening of prognosis. The study objective was to estimate the frequency of patients with missed cancers in the Danish HNC fast-track program and to evaluate the accuracy of the program.

Methods
Patients who were rejected from the HNC fast-track program because cancer was not found between 1 July 2012 and 31 December 2018 at Odense University Hospital, Denmark were included and followed for three years. Patients were categorized into groups depending on the diagnostic evaluation. Group 1 included patients evaluated with standard clinical work-up without imaging and biopsy. Group 2 included patients evaluated with imaging and/or biopsy in addition to the standard clinical work-up. The local cancer database and electronic patient records were reviewed to determine if a missed cancer had occurred within the follow-up period.

Results
A total of 8345 HNC fast-track courses were initiated during the study period. 1499 were patients suspected of recurrent cancer and were excluded leaving 6846 patients to be assessed for eligibility. Of these, 3752 patients were rejected because cancer was not found. Ten patients were subsequently diagnosed with cancer within the follow-up period resulting in an overall frequency of 0.15%. For group 1 and 2, the frequency was 0.04% and 0.10%, respectively. The sensitivity of the fast-track program was 99.67% and the negative predictive value was 99.73%.

Conclusion
The frequency of missed cancer in a tertiary HNC center following the Danish fast track program is low.

iii: Sprogbaseret ulighed i kræftbehandling – observation af sprogbarrierer i klinisk praksis

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Abstract

Introduktion
Når samtalen drejer sig om kræft, kan sprogbarrierer få alvorlige konsekvenser. På trods heraf har kommunikationen mellem sundhedsprofessionelle og patienter med kræft og begrænsede danskfærdigheder hidtil ikke været undersøgt. Formålet med dette studie var at undersøge kommunikationen i det direkte møde mellem kræftlæger og -sygeplejersker og patienter med begrænsede danskfærdigheder. Fokus var særligt på, hvordan de sproglige barrierer påvirkede patientinddragelse og beslutningstagning.

Materialer og metoder
Med et kvalitativt forskningsdesign gjorde studiet brug af deltagerobservation. Der blev i alt observeret 18 kliniske møder på to af landets kræftafdelinger. Møderne bestod af såvel lægesamtaler som kemo- og immunterapibehandlinger. Kommunikationen blev lydoptaget og efterfølgende transskriberet og analyseret sammen med håndskrevne feltnoter fra observationerne.

Resultater
På baggrund af analysen blev følgende tre temaer identificeret: Miskommunikation og usikkerhed som sprogligt grundvilkår; Tidens betydning for patientinddragelse; Ulige fordelte roller og (mis)kommunikationsansvar. Resultaterne viser, at professionel tolkning ikke kunne udrydde miskommunikation, men var afgørende i forhold til at kunne komme frem til en forståelse. Organisatoriske forhold og herunder øget tidspres forbundet med tolkning begrænsede patientinddragelsen. Uden professionel tolkning blev patienternes pårørende pålagt et massivt ansvar for kommunikationen. Når der hverken var professionelle tolke eller dansktalende pårørende til stede, blev både lægernes og sygeplejerskernes etiske dilemmaer væsentligt øget sammen med risikoen for fejl.

Konklusioner
Sprogbarrierer har ikke kun konsekvenser for patienten, der ikke taler flydende dansk, men for alle, der deltager i kommunikationen. Studiet viser, hvordan sprogbarrierer kommer til udtryk i klinisk praksis og kan således bruges i indsatser rettet mod at reducere sprogbaseret ulighed i kræftbehandling.

iv: Stick Together – Feasibility study of a digital dyadic intervention for younger women with breast cancer and their partners

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Abstract
Introduction
Few psychosocial interventions target younger women with breast cancer (BC) and their partners, despite their special circumstances and high levels of distress. Couples' dyadic coping has been shown to have significant effects on relationship quality and depressive symptoms. The ongoing study aims to 1) test the acceptability and feasibility of a digital, interactive intervention designed to improve dyadic coping for younger BC patients and their partners, and 2) evaluate preliminary effects on dyadic coping and mental health.

Materials & Methods
Over six months, we invited women newly diagnosed with BC, aged 25 to 49, and their partners at the Department of Breast Surgery, Gentofte Hospital. All couples received access to twelve self-directed sessions, containing video-interviews with other couples, psychoeducation, and exercises on e.g., dyadic coping, communication, fertility and children, and life after treatment. We track intervention use (frequency, duration, and content accessed), assess dyadic coping, depression, anxiety, stress, and quality of life at baseline, mid- and post intervention, and conduct semi-structured interviews after participation.

Results
From February to July 2023, we included 22 couples. Eighteen couples completed the intervention course, and four withdrew citing limited time and energy. Preliminary feasibility results include a 47% consent rate among eligible couples, large variation in intervention use (mean per couple: 306 minutes, range: 46 to 688), and longer time to completion for some couples (up to 8 months vs. expected 6 months). Complete data on intervention use and results on questionnaire outcomes will be presented.

Conclusion
Based on the consent rate at a time of substantial strain, the intervention seems relevant to couples, yet there was large variation in intervention use and completion.

v: Sexual health in patients with malignant hematological disease: a Danish cross-sectional study

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Abstract

Purpose
This study investigated the prevalence of sexual dysfunction and factors influencing sexual activity and functioning in patients with hematologic malignancies, to identify potential targets for interventions in clinical practice.

Methods
This nationwide cross-sectional study included adult patients diagnosed with a hematologic malignant disease in Denmark in the period from 20/1-2013 to 20/8-2022. Eligible participants received electronic questionnaires through their officially assigned digital mailbox; including the Female Sexual Function Index, International Index of Erectile Function Questionnaire, Female Sexual Distress Scale – Revised, The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Sexual Health and The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire.

Results
A total of 362 patients, on average 5.7 years (SD: 3.4) post diagnosis, completed the questionnaires. Of these, 52.5% women and 73.2% men reported sexual dysfunction with more females (40.9%) than men (34.1%) being sexually inactive. Across gender this was significantly more prevalent in patients >65 years and in those with a low quality of life. In addition, for women a significant association with fatigue and sleep difficulties was observed. In total, 40.3% reported sexually related personal distress with the highest proportion among patients aged 40-65 years. Most patients (98.7%) with sexual dysfunction had not discussed sexual issues with their health care professional.

Conclusion
Patients report a high prevalence of sexual dysfunction, sexual distress, and gender-specific sexual symptoms following diagnosis and treatment of a malignant hematologic disease, impacting their quality of life. Hence, healthcare professionals need to proactively address and discuss sexual health issues with the patients, irrespective of age.

vi: ProTarget – An investigator-initiated Danish Nationwide Clinical Trial on Targeted Cancer Treatment based on Genomic Profiling. Trial, Overview and Status

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Abstract
Introduction
An increasing number of trials indicate that patient outcomes improve when targeted treatments are matched with actionable genomic variants in individual patients (pts). However, as personalized cancer treatment is often used off-label/off-protocol without data collection, the efficacy of personalized cancer treatment remains insufficiently studied and documented. ProTarget is a trial aiming to collect these data and evolve personalized cancer medicine.

Materials and Methods
ProTarget is a national, investigator-initiated, non-randomized, multi-drug, open-label, pan-cancer phase II trial. The trial investigates anti-tumor activity and toxicity of 13 commercially available, EMA-approved targeted drugs used off-label for advanced malignant diseases with actionable genomic variants. Key inclusion criteria include a) RECIST 1.1 measurable disease, b) ECOG performance status 0-2, and c) a drug-variant match confirmed by the Danish National Molecular Tumor Board. Key exclusion criteria include a) cancer type within the EMA-approved label of the selected drug, and b) genomic variants known to confer drug resistance. The primary endpoint is objective response or stable disease at 16 weeks. Patients are

assigned to cohorts defined by the selected drug, genomic variant, and tumor type. Extensive translational research is performed using whole genome and RNA sequencing, and deep visual proteomics on serial fresh tumor and liquid biopsies and used for e.g., validation of AI-based Clinical Decision Support tools.

Results
Since 2020, 262 pts across >30 cancer diagnoses have been enrolled in treatment across 148 cohorts with 189 serious adverse events reported. Two cohorts have been expanded to stage 2 due to observed clinical benefit in ≥1 of 8 pts. enrolled.

Conclusion
National efficacy and safety data are successfully collected and pooled with other similar European trials. ProTarget provides us with valuable insights in the efficacy of personalized cancer care

vii: Risk of Recurrence in Early-onset vs. Late-onset Non-metastatic Colorectal Cancer: A Nationwide Cohort Study 2004-2019

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Abstract
Introduction
The incidence of colorectal cancer (CRC) in individuals under 50 (early-onset CRC) is increasing, and early-onset CRC is often diagnosed with advanced disease stage, raising the question of aggressive tumor biology. This study estimates and compares incidence of recurrence following early-onset CRC to late-onset CRC (age 50-79) from 2004 to 2019.

Material and methods
This nationwide cohort study included all Danish patients operated for UICC stage I-III CRC between January 2004 and December 2019. Recurrence status was determined by applying a validated algorithm to data from nationwide health registries. The 5-year cumulative incidence functions (CIF) of recurrence were reported for early-onset vs. late-onset CRC, and subdistribution hazards ratios (Fine-Grey regression: sHR, 95% CI) were reported by calendar periods (2004-2008, 2009-2013, and 2014-2019). The difference in time to recurrence was estimated as a time ratio (TR) using an accelerated failure time model.

Results
Among 25,729 CRC patients, 1,441 (5.6%) had early-onset CRC. Compared to late-onset CRC, early-onset was associated with advanced disease stages and higher treatment intensity. The 5-year CIF of recurrence was 29% (95% CI: 26%-31%) in early-onset vs. 21% (95% CI: 21%-22%) in late-onset CRC. Time to recurrence was shorter in early-onset vs. late-onset patients with TR=0.76 (95% CI: 0.67-0.85).
The 5-year CIF of recurrence decreased from 2004 to 2019 for both early and late onset patients - most prominent for early-onset patients. Hence the excess risk of recurrence for early-onset CRC decreased from sHR=1.43 (95% CI: 1.21-1.68) in 2004-2008 to sHR=1.31 (95% CI: 1.10-1.57) in 2009-2013, and to sHR=1.10 (95% CI: 0.90-1.34) in 2014-2019.

Conclusions
Early-onset CRC was associated with higher risk of recurrence, but the excess risk diminished from 2004 to 2019, suggesting that early-onset CRC may achieve a similar risk of recurrence when treated according to modern guidelines.

1. Clinical trials I #1-10

#1: Effect of comprehensive geriatric assessment on hospitalizations in older patients with frailty initiating curative oncologic treatment – the PROGNOSIS-RCT study

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Abstract
Introduction
The aim was to examine the impact of adding a comprehensive geriatric assessment (CGA) to oncologic care in preventing hospitalizations in older adults with frailty initiating curative treatment.

Methods
This randomized controlled trial included older adults aged ≥70 with frailty (Geriatric 8 ≤14), and solid cancers initiating curative treatment. Participants were randomized 1:1 to either standard oncologic care (control) or standard oncologic care supplemented with CGA-guided interventions (intervention). The between-group rate ratio in hospitalizations within the first six months (primary endpoint) was calculated using negative binominal regression adjusted for time at-risk with an intention-to-treat approach, followed by per-protocol analysis (participants receiving CGA within 30 days of randomization).

Results
From November 1 2020 – May 31 2023, 173 participants were enrolled. Median age was 75 (IQR 72 – 79), 51.5% were women, 58% had a G8 score > 12, and 84% had PS 0-1. The most common cancer sites were lung (23%) and upper gastrointestinal (15%). The rate (per person-years) in unplanned hospitalization was 1.32 in the intervention group and 1.81 in the control group, with a between-group rate ratio of 0.74 (95% CI 0.45 – 1.23, P = 0.25) favoring the intervention. The between group rate ratio increased in the per-protocol analysis (0.64 (95% CI 0.37 – 1.10, P = 0.10)) remained
non-significant.

Conclusion
Although this study did not find an impact of CGA on unplanned hospitalizations, per-protocol analysis suggests that measures increasing adherence to CGA may increase the overall effect. Larger studies are required to confirm our findings.

#2: Validating the ESTRO target consensus: pattern of breast cancer failures in the DBCG Skagen trial 1

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Abstract
Introduction
The phase III randomized clinical DBCG Skagen trial 1 (NCT02384733) randomized 2080 node-positive Danish breast cancer patients (pt) 50Gy/25fr versus 40Gy/15fr for loco-regional radiotherapy (RT) during 2015-2021. All target volume delineation had to follow the ESTRO consensus guideline for target volume delineation in early breast cancer and a report of loco-regional pattern of failure according to ESTRO guideline was pre-specified in the trial protocol to validate the clinical feasibility of the ESTRO guideline in high-risk breast cancer pt. Here we present the first analysis of the pattern of failure in pt from the DBCG Skagen trial 1.

Materials and methods
Loco-regional failure with or without distant failure as the first event was defined from all available imaging and matched with the planning CT scan, and classified as inside the CTV, inside the high-dose volume, at the edge of the high-dose volume, or outside.

Results
At a median follow-up of 4.5 years, locoregional recurrence was present in 53 pt; 28 pt with isolated locoregional failure and 25 with locoregional failure concurrent with distant failure. All pt except two had the loco-regional failure in the high-dose volume. Of the 28 pt with isolated loco-regional failure, all failures were in the high-dose volume. Of the 26 pt with loco-regional failure with concurrent distant failure, two had nodal failure at the edge of the high-dose volume.

Conclusion
The majority of loco-regional failures in high-risk breast cancer pt treated with adjuvant radiotherapy according to the ESTRO guideline and diagnosed with loco-regional failure were detected inside the high-dose volume of radiation. This pattern of failure is in strong support of the feasibility of the ESTRO consensus guideline indicating that there appears no need to expand the size of the nodal targets. As pre-specified, the loco-regional pattern of failure for the entire cohort in the DBCG Skagen trial 1 will be performed.

#3: DAHANCA 37:Gen-bestråling af hoved-halskræft med proton-strålebehandling (NCT03981068)

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Abstract

Introduktion
Hvis man én gang er strålebehandlet mod hoved-halsområdet er det problematisk at give en ny strålebehandling for et tilbagefald eller en ny kræftknude, pga. risikoen for alvorlige, inklusiv livstruende, bivirkninger. Strålebehandling med protoner kan nedsætte den samlede stråledosis til patienten, og måske risikoen for alvorlige bivirkninger.

Materialer og metoder
DAHANCA (den Danske Hoved-Halskræft Gruppe) udfører en fase II protokol med vide inklusionskriterier. Den oprindelige stråleplan skal være til rådighed således at man kan lave en samlet dosisplan for både den oprindelige og den aktuelle dosisplan. Patienterne diskuteres på en national konference før henvisning. Egnede patienter vil blive tilbudt hyperfraktioneret strålebehandling med 60 Gray på 50 behandlinger, 10 behandlinger om ugen. Det primære endepunkt er nye alvorlige bivirkninger (CTC grad ≥ 3). Vigtige sekundære endepunkter bliver tumorkontrol, patient rapporterede symptomer og livskvalitet. Det er planlagt at inkludere 20 patienter.

Resultater
13 patienter, 47-87 år, er behandlet i protokollen siden 1. kvartal 2020. Patienterne fordeler sig med 42% recidiver og 58% nye primær tumorer. Alle patienter, undtagen en, havde planocellulært carcinom. Syv yderligere patienter blev diskuteret på videokonference og ikke tilbudt behandling i protokollen, enten fordi der ikke var dosimetriske fordele eller fordi strålebehandling i det hele taget ikke blev anbefalet. Der er en patient der er død af blødning, sandsynligt behandlingsrelateret. Generelt er der henvist færre patienter til denne protokol.

Konklusion
Med de tilgængelige samlede dosisplaner og adgang til strålebehandling med protoner mener vi at kunne tilbyde patienten skånsom strålebehandling. De tidligste erfaringer viser at det er produktivt at diskutere

patienterne nationalt, og udvikle mere ens kriterier for patient udvælgelse. Med studiet får vi ny viden om de forventede bivirkninger og den optimale udvælgelse af patienterne.

#4: Behandling af planocellulært karcinom i anale margin med ”Eye-guided” elektron strålebehandling

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Abstract
Baggrund
Planocellulært karcinom i anale margin er en sjælden kræftform, der udgør mindre end 25% af alle anal cancere. Små tumorer behandles med kirurgi eller strålebehandling, mens større tumorer behandles med kemoradioterapi. På Onkologisk Afdeling, Vejle Sygehus, er selekterede patienter strålebehandlet med et perinealt elektronfelt. Teknikken mindsker risikoen for et ”geografisk miss”, idet strålebehandlingen afgives under ”eye-guidence”. Elektive lymfeknuder medbestråles ikke, hvilket kan øge risikoen for regionalt recidiv.

Metode
Der blev inkluderet 40 patienter i perioden fra 2012 til 2022. Lokal kontrol (LK) og overlevelse (OS) er analyseret ved hjælp af Kaplan-Meier-statistik. Lokalrecidiv og sen toksicitet er analyseret deskriptivt i forhold til elektrondosis og energi.

Resultater
Fordelingen af TNM-stadie er 65,0% og 35,0% for henholdsvis T1N0M0 og T2N0M0 tumorer. Median ordineret stråledosis er 60,0 (45,0-60,2) Gy på 28 (10-30) fraktioner, leveret med 8 (4-18) MeV på standard tube. Efter en median opfølgning på 73 (9-135) måneder var 7 (17,5%) patienter diagnosticeret med lokalrecidiv. 5-års LC-rate var 84,3%. Analyse af LK i forhold til T-stadie viste en 5-års LK på 100% og 57% for henholdsvis T1 og T2 tumorer (p<0,001). 5-års OS var 91,6%. Der blev ikke diagnosticeret nogle solitære regionale recidiver. Sen grad 3 toksicitet inkluderede ulceration i hud og subcutis hos 2 (5,0%) patienter, en tredje patient (2.5%) oplevede grad 2 anal inkontinens.
Der blev ikke fundet sammenhæng mellem lokalrecidiv og elektrondosis eller -energi. Patienter der havde grad 2-3 morbiditet var behandlet med høje elektronenergier på 15-18 MeV sammenlignet med de resterende patienter, der blev behandlet med lavere energier på 4-12 MeV.

Konklusion
Elektronstrålebehandling giver fremragende LK hos patienter med T1-tumorer. Energivalget anbefales ikke at ligge højere end maksimalt 12 MeV. Patienter med T2-tumorer har mindre god LK og bør behandles med kemoradioterapi.

#5: Re-irradiation of anal cancers – the importance of EQD2 correction for meaningful dose accumulation to prevent unnecessary target compromises – The ReRad III/DACG V study

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Abstract
Introduction
Proton therapy is highly eligible for reirradiation. Correct dose summation is important for radiobiological evaluation of accumulated doses to Organs at Risk (OAR). With new software solutions it is possible to perform voxel-by-voxel (v-b-v) fractionation corrected doses to avoid both unintended overdosage to OAR or unwanted target coverage compromises. We aimed to determine the diff erence between EQD2-corrected and uncorrected physical dose summations.

Materials and methods
Seven patients included in the ReRad III/DACG V trial (dose escalated proton reirradiation for anal cancer recurrences) all treated with hyperfractionated Intensity Modulated Proton Therapy (IMPT) 55-65Gy. Both previous and reirradiation plans were v-b-v Equivalent Dose in 2Gy Fractions (EQD2) corrected in Velocity AI. Subsequently both plans were accumulated in Eclipse as physical dose (ph) and EQD2-corrected dose. For the v-b-v EQD2-correction we used an $\alpha/\beta=3$. We used rigid 6D-registration between CTs, focusing on dose overlap regions.

Results
Mean of the accumulated max and mean doses for - Bladder: Max 85.9 Gy(EQD2) (range:55.2-117.9) to 95.8 Gy(ph) (61.2-126.6); Mean 36.2 Gy(EQD2) (16.6-46.1) to 41.0 Gy(ph) (19.5-53.4).- Bowel loops: Max: 84.1 Gy(EQD2) (60.1-117.0) to 92.9 Gy(ph) (58.9-126.4); Mean 36.8 Gy(EQD2) (7.5-73.1) to 42.8 Gy(ph) (9.4-82.0).- Ipsilateral ureter: Max: 92.6 Gy(EQD2) (67.5-117.7) to 106.3 Gy(ph) (80.2-126.8); Mean 63.0 Gy(EQD2) (36.4-92.2) to 70.5 Gy(ph) (37.7-101.3).Similar diff erences (EQD2-ph) ~10 Gy for max and ~5 Gy for mean doses where found for contralateral ureter, sacrum and femoral heads.

Conclusion
We found deviations between physical and EQD2-corrected dose summation in the range of 10 Gy in max and 5 Gy in mean dose across patients. This will very likely translate into unnecessary target coverage compromises or unintended OAR dosage. These results underline the importance for 3D fractionation correction before dose summation.

#6: Living with Oligometastases: Preliminary PROs & QoL in the SOFT MR-Guided SABR Multicenter Trial

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Abstract
Introduction
The SOFT multicenter phase II trial included patients with infradiafragmatic oligometastases for online MR-guided stereotactic ablative radiotherapy (MRgSABR) (clinicaltrials.gov ID NCT04407897). There is limited knowledge about patient-reported toxicity and health-related quality of life (HRQoL) for this patient group treated with SABR. The purpose of this study was to investigate changes in patient reported toxicity six months following MRgSABR and HRQoL in the one-year follow-up period.

Materials and methods
Patients from four RT centres in two countries participated receiving 3-8 fractions. Patients received a link for the ePRO system (REDCap). At six time points (baseline, end of RT, week 2, 6, 12 and 24) patients reported eight symptomatic AEs from the Patient-Reported Outcomes version of the CTCAE (PRO-CTCAE). For HRQoL, the EQ-5D-5L questionnaire was used until week 52.

Results
The study enrolled 121 patients, with 24% having more than one target. The median age was 69, the majority had oligometastatic recurrence (59%) or progressive disease (32%).
Overall, HRQoL was stable throughout the one-year follow-up after SABR, with the mean EQ-5D index value returning to baseline level week 52 (mean 0.827 (SD 0.15)) declining the most in week 24 (mean 0.813 (SD 0.17)). Fatigue was the most common symptom reported above baseline severity by 53% of patients post MRgSABR. For the majority, fatigue was mild but for 16%, moderate to very severe. The frequency of nausea and diarrhoea above baseline level was 30% and 33%, respectively. Both symptoms were most frequent at the end of MRgSABR.

Conclusion
Online MR-guided SABR for infra-diaphragmatic soft tissue metastases results mainly in mild to moderate symptoms in the patients' self-reports, with fatigue, diarrhoea, and nausea being the most frequent. The

relation between HRQoL and symptoms and patients receiving systemic treatment in the follow-up period are still to be investigated.

#7: Examining Photon and Proton Radiotherapy Plan Quality in the Clinical Head and Neck Trial DAHANCA 35

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Abstract
Introduction
The primary objective of radiotherapy treatment planning is to achieve optimal target coverage while minimising the radiation dose to critical Organs at Risk (OARs) following relevant guidelines. Ensuring consistently high-quality radiotherapy plans is crucial for patients' survival chances and risk of side effects. The importance of treatment plan quality is emphasised in The Danish Head and Neck cancer Study Group (DAHANCA) 35 trial of proton versus photons, where patients are selected on treatment plan comparisons. This study evaluates the plan quality in DAHANCA 35.

Materials and methods
193 patients were enrolled from September 2019 to June 2023 based on a simulated benefit in normal tissue complication probability (NTCP) for proton therapy by comparing patient photon and proton treatment plans. A new clinical proton plan was made for patients randomised for proton therapy. All treatment plans followed the DAHANCA radiotherapy guidelines.
Splitting patients into three time-intervals, plans were assessed using NTCP for dysphagia grade 2+, mean dose to 13 OARs relevant to head and neck cancer, and a new metric: Normalised Toxicity Index (NTI), calculating the normalised average of the mean dose to the OARs compared to the recommended thresholds outlined in the DAHANCA guidelines.

Results
99% of the 529 analysed plans met the guidelines for target coverage and critical OAR dose.
There was no significant difference between the three time intervals for both NTCP, mean dose, and NTI for all three plan types.

NTI was significantly higher for photon plans than comparative and clinical proton plans.

Conclusions
A consistent treatment plan quality ensures a robust patient selection for the clinical trials. It enables transparency in the trial outcome analysis and ensures the reliability of trial results. The ongoing monitoring of plan quality is set in place to ensure consistency.

#8: Home based daratumumab treatment guided by Patient Reported Outcome data in patients with multiple myeloma

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Abstract
Introduction
Multiple myeloma survival has improved significantly, but it remains incurable with lifelong treatment needs. Together with global challenges of demographic shifts, this calls for new approaches for future treatment. Here, treatment relocation and use of electronic Patient Reported Outcome (PRO) data are gaining ground.

Materials and methods
From April 2022 to June 2023, 18 patients receiving daratumumab for ≥6 cycles and 12 patients new on daratumumab were included. New patients received six 28-day cycles of daratumumab with every second treatment given by a district nurse at home or in a local healthcare clinic. Patients already on treatment were followed for 7 cycles with two of three treatments given outside the hospital. Prior to treatment, PRO data on side effects was collected electronically and an algorithm was developed to stratify patients according to treatment readiness. Patients also had a telephone consultation with a nurse.

Results
Of 123 hospital-planned administrations, 122 (97.6%) were given. Of 144 outsource administrations, 133 (92.4%) were given as planned, six (4.2%) were redirected to the hospital, and five (3.4%) were cancelled. There was no significant difference between the numbers of cancellations/redirections between hospital and home treatments. Patients spent significantly less time on outsourced treatment compared to hospital treatment, even if travel time was deducted. Reducing the patients' visits to the hospital did not cause additional unplanned contacts to the healthcare system. With a cost of a low negative predictive value, collection of PROs and the associated algorithm showed a positive predictive value of 100%. Patients were satisfied receiving treatment at home and reporting side effects themselves; 84% of patients were in favor of continued home treatment.

Conclusions
Administration of daratumumab by a district nurse is feasible and preferable. PRO data effectively evaluate patients prior to treatment.

#9: Short course immunotherapy as curative-intended treatment in stage I-III dMMR rectal cancer. A DCCG, phase 2 study

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Abstract

Background

Neoadjuvant chemo-radiation followed by resection is standard treatment for patients with locally advanced rectal cancer (RC). A subset of RC are mismatch repair deficient (dMMR). Check-point inhibitors (CPI) are the standard of care in dMMR colorectal cancer (CRC) in the metastatic setting, and recent trials have demonstrated impressive efficacy in early CRC, even with a limited number of cycles. In the NICHE-II trial (Chalabi et al) 72 of 107 patients with colon cancer obtained pathological complete response (pCR) after short course CPI. In patients with RC, Cercek et al showed that 12 patients (100%) obtained pCR after 6 months of dostarlimab. The efficacy of CPI in dMMR RC has only been evaluated in few studies. Here we report data from a DCCG, phase 2 trial with early dMMR RC. EU CT number 2022-500646-14-00.

Methods

The purpose was to evaluate the efficacy and tolerability of 1 cycle of nivolumab (3 mg/kg days 1 and 15 - nivo) and ipilimumab (1 mg/kg day 1 - ipi) in patients with early stage dMMR RC. The primary endpoint was number of patients with clinical complete response (cCR - no visible or palpable tumor) evaluated 93 days after nivo-ipi. Patients achieving a clinical, radiological, pathological (representative biopsy without viable tumor cells), and molecular complete response was offered a thorough watchful waiting strategy without surgery.

Results

6 patients were treated, 45patients received a single cycle of nivo-ipi and 1 patient received 2 cycles of nivo-ipi, as the tumor was still visible at the first endoscopy. 5 patients were evaluated 93 days after completing nivo-ipi and all 5 patients (100%) achieved cCR. No patient needed radiotherapy and all patients agreed to non-surgical watchful waiting. No patient has had progression or recurrence (ongoing-14 months follow-up).

Conclusions
Short-course nivo-ipi is very effective in locally advanced dMMR rectal cancer and may become an alternative to resection.

#10: Loco-regional control following heterogeneous FDG-guided dose-escalation for locally advanced NSCLC in the international phase III NARLAL2 trial

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Abstract
Background
The survival and tumor control for patients (pts) with locally advanced non-small cell lung cancer (LA_NSCLC) treated with radiotherapy (RT) are dismal. A novel approach is therefore warranted to escalate the dose to tumor. A possible approach is to use inhomogeneous dose distribution.
The international multicenter NARLAL2 (novel approach to RT for LA_NSCLC) phase III trial on dose escalation, randomized pts with LA_NSCLC between standard 66 Gy/ 33 fractions (F) versus heterogeneous FDG-PET driven dose escalation, aiming at mean dose to GTV-tumorPET 95 Gy/ 33 F while strictly respecting dose to organs at risk.
We here present the data on overall survival (OS) 1 year after end of recruitment.

Methods
Pts aged ≥18 years with LA_NSCLC were recruited from seven institutions in Denmark and Norway.
Eligibility criteria included PS 0-1, NSCLC stage IIB-IIIB, signed informed consent.
Pts were randomly assigned to either treatment group (1:1). The trial aimed to have iso-lung toxicity within the treatment arms.
The follow up (FU) were scheduled up to 10 years after randomization.
The trial's primary endpoint was time to loco-regional failure from randomization. Secondary endpoints included OS and toxicity.
The sample size calculations requested 350 pts to be enrolled in the study. The study finalized recruitment in March 2023.
The trial was registered with ClinicalTrials.gov (NCT02354274).

Results
From Jan 2015 to Mar 2023, 350 pts were randomized; 177 and 173 pts in standard and escalated arm respectively. The two groups were well balanced; with respect to age, gender, stage, and PS. The dose to GTV-tumor was 66.5 Gy [66.2, 67.1] (median [IQR]) in standard arm and 87.9 Gy [84.4, 90.4] in the escalated arm. Median OS were 35.8 months for pts treated in the standard arm, whereas mOS were 51.8 months for pts treated in the escalated dose arm (p=0.36).

Conclusion
Dose escalation is safe in the setting of NARLAL2 with respect to OS.

2. Clinical trials II #11-20

#11: Treatment of Breast Cancer-Related Lymphedema with Topical Tacrolimus: A 12 month Prospective, Phase II Pilot Trial

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Abstract

Introduction
Breast cancer-related lymphedema (BCRL) presents a signifi cant challenge in breast cancer survivorship due to limited treatment options. Tacrolimus, an immunosuppressive agent, has shown promise in preclinical models for reducing lymphedema. This study aimed to assess effi cacy and durability of topical tacrolimus treatment in patients with BCRL.

Methods
Eighteen women with stage I or II BCRL were enrolled in this study. The participants underwent six months of tacrolimus treatment. Assessments were made at baseline with follow-up at 3, 6, and 12 months. Thus, the 12 months follow-up took place six months after the treatment had stopped. The primary endpoint was arm volume measured with; i) water displacement and ii) tape measurements. Secondary endpoints included lymphedema-index, quality of life, lymphatic fl ow and function, and use of concomitant lymphedema treatment.

Results
Results at six months demonstrated signifi cant reductions in arm volume measured with water displacement and tape measurements, lymphedema-index, and use of concomitant treatment. Quality of life improved signifi cantly. The 12 months follow-up showed continued signifi cant reductions in arm volume measured with tape measurements. Furthermore, quality of life, and use of concomitant treatment remained signifi cantly improved from baseline. Lymphatic fl ow- and function exhibited discrepant results.

Conclusion
Topical tacrolimus demonstrated short-term effi cacy in reducing BCRL symptoms and improving quality of life. The durability of these eff ects varied, with some measures returning to baseline levels at six months post-treatment cessation. Larger, randomized controlled trials are warranted to validate these findings and explore the role of maintenance treatment with topical tacrolimus in BCRL management.

#12: Topical Tranexamic acid in mastectomies on hematoma formation: A prospective cohort study

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Abstract
Background
Tranexamic acid (TXA) has been suggested to reduce hematoma formation after breast surgery. Existing literature, however, presents inconsistencies regarding the methods of administration and dosages for topical application.This study aims to investigate the eff ect of perioperative administration of topical TXA on mastectomy procedures, focusing on postoperative hematoma formation and drain output.

Methods
The study cohort was included during October 2020 until September 2023 and comprised two consecutive periods. In the fi rst, the control group, included women undergoing mastectomy and receiving no TXA. In the second period, all women undergoing mastectomy received 20ml of 50mg/ml TXA retrogradely into the drain immediately after closure of the cavity. In both groups most women had either axillary clearance or sentinel node biopsy done in addition to the mastectomy. All medical records were thoroughly scrutinized for information on the primary outcomes; hematoma formation requiring surgical intervention and mean drain output 24 hours postoperatively. Several other possible confounders as age, BMI, smoking, and use of anticoagulant were also registered. This study was designed in accordance with STROBE guidelines.

Results
Among 271 women (297 breasts) receiving topical TXA and 264 women (278 breasts) serving as a control group, 4 (1.4%) and 19 (6.8%) women, respectively had surgical revisions due to hematoma. This was statistically signifi cant (p=0.005). Furthermore, the TXA group demonstrated a signifi cantly lower mean drain output within the fi rst 24 hours postoperatively, averaging 67.6ml compared to 103.9ml in the control group (p=0.001).

Conclusion
Administering 20ml of 50mg/ml topical TXA retrogradely into the drain after skin closure signifi cantly reduces the incidence of hematoma formation by approximately 79%, as well as the mean drain output within the fi rst 24 hours following a mastectomy.

#13: Association between functional exercise capacity, physical activity levels, and Health-Related Quality of Life among vulnerable lung cancer patients at diagnosis: A cross-sectional study

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Abstract
Introduction
Vulnerable lung cancer patients are at risk of impaired Health-Related Quality of Life (HRQoL), and modifi able factors, like exercise or physical activity, could potentially alleviate this problem. The aim was to examine the association between Functional Exercise Capacity (FEC), weekly physical activity, and HRQoL among screened vulnerable lung cancer patients participating in the NAVIGATE RCT study.

Materials and methods
Using multiple linear regression, we investigated the cross-sectional association between objectively measured FEC (6-minute walking distance, handgrip strength and 30-second sit-to-stand), self-reported weekly physical activity, aerobic activity, and daily sedentary time, as well as HRQoL (EORTC QLQ-C30 and EORTC QLQ-LC13) at time of diagnosis.

Results
Participants were 125 lung cancer patients with median age of 72 years. We found that greater functional aerobic fitness, muscular function, weekly physical activity, and less daily sedentary time were significantly

associated with higher levels of physical functioning and role functioning ($p < 0.01$). Moreover, higher functional aerobic fitness was associated with lower levels of dyspnoea (β) -0.07 (99% CI -0.12 ; -0.01), while less daily sedentary time was associated with higher emotional functioning, and lower fatigue ($p < 0.01$). Finally, higher weekly physical activity was associated with higher Quality of Life (β) 3.06 (99% CI 0.14 ; 5.99).

Conclusions
Higher levels of functional aerobic fi tness, muscular function, and weekly physical activity, along with less sedentary time, were associated with higher HRQoL and lower disease-specifi c symptom burden. Clinicians should stress the importance of increasing FEC, physical activity levels and decreasing sedentary time among lung cancer patients already at time of diagnosis and thus prior to treatment.

#14: Identifying safe diagnostic algorithms for sentinel lymph node mapping in high-risk endometrial cancer: the SENTIREC-endo study

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Abstract
Introduction
In the treatment of endometrial cancer (EC), surgical staging serves to allocate women with metastases to adjuvant therapy. It is unclear, if it is diagnostically safe to replace the current standard of both pelvic- (PLD) and paraaortic lymphadenectomy (PALD) with SLN mapping, to women with high-risk EC. When performing SLN mapping, 20–48% will have failed uni- or bilateral SLN mapping. Thus, surgical algorithms need to consider failed mapping cases. We aimed to identify potential SLN mapping algorithms, to replace PLD and PALD in women with high-risk EC.

Materials and methods
A national prospective diagnostic cohort study from March 2017 to January 2023. Women underwent SLN mapping, PLD and PALD besides the removal of any clinically suspicious- and FDG/PET-positive lymph nodes. Accuracy analyses were performed for five surgical algorithms. The sensitivity and NPV of the SLN algorithms were estimated with 95% one-sided exact Clopper–Pearson confidence intervals.

Results
Of the 216 women included, 170 underwent SLN mapping, PLD, and PALD and were included in accuracy analyses. Nodal metastases were present in 24.7% (42/170). The algorithm SLN and PLD in case of failed mapping, demonstrated a sensitivity of 86% (95% CI 74-100) and an NPV of 96% (95% CI 91-100). This increased to, sensitivity 93% (95% CI 83-100) and NPV 98% (95% CI 94-100) if PLD was combined with removal of any PET-positive lymph nodes. The same sensitivity and NPV were obtained if PLD and PALD were performed in non-mapping cases without using PET-imaging.

Conclusion
SLN-mapping is a safe staging procedure in women with high-risk EC if strictly adhering to a surgical algorithm including removal of any PET-positive lymph nodes and PLD in case of failed mapping. For centres lacking confidence in the interpretation of FDG-PET/CT, PLD and PALD are required in cases of failed mapping. The results have led to changed clinical guidelines and less extensive surgery in women with high-risk EC.

#15: Exploring perspectives on a hospital-based smoking cessation intervention in the context of transurethral resection of the bladder: a qualitative study

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Abstract
Introduction
Tobacco smoking significantly contributes to bladder cancer development, contributing to up to 50% of cases. Continued smoking after diagnosis may impact disease progression and recurrence. While smoking cessation appears to provide a protective effect. However, limited studies focus on smoking cessation intervention (SCI) related to bladder cancer treatment. This study aimed to explore the perspectives of surgical patients, their relatives and healthcare professionals on a hospital-based SCI initiated alongside transurethral resection of the bladder.

Materials and methods
We explored the hospital-based SCI through a qualitative design with semi-structured individual interviews. Participants were recruited from an ongoing randomized controlled trial comparing an intensive smoking cessation intervention via the municipality clinic compared to the surgical department. Patients nominated relatives for participation, and healthcare professionals were recruited from the department. Data analyses were conducted according to the Framework method. The study was approved by Danish Scientific Ethical Committee.

Results
In total, 18 persons (eight SCI participants, four relatives and six health care professionals) were interviewed. Preliminary findings from SCI participants indicate a meaningful perception of the offered SCI. Facilitators highlighted include the provision of information about the link between bladder cancer and smoking, positive reinforcement, and flexibility in the planning of the SCI meetings. Conversely, barriers encompassed being alone, the physical dependency, meetings in conflict with daily life, and symptom management. The analytical work is ongoing, and we anticipate presenting comprehensive findings at the august 2024 conference.

Conclusions
The multi-perspective interview study will offer insights into preferences, barriers, and facilitators in relation to a SCI in relation to the bladder cancer treatment pathway.

#16: Physical function following megaprosthesis surgery in the lower limb - a prospective cohort study of 38 patients

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Abstract
Introduction
Limited knowledge exists on early outcomes post-megaprosthesis surgery. Yet, in counseling of patients understanding these outcomes is crucial. This prospective study investigates physical function outcomes in lower limb megaprosthesis surgery patients, employing both objective and subjective measures, while also identifying their associations.

Materials and methods
38 patients underwent treatment with a proximal femur, distal femur, or proximal tibia megaprosthesis. Muscle strength tests, range of motion evaluations, the Timed Up and Go test, and the Musculoskeletal Tumor Society score were conducted at 4, 8, and 12-18 months post-surgery. Repeated measurements analysis was performed along with a comparison between treated limb, untreated limb, and predictive values.

Result
Bilateral muscle strength reduction, especially in regions subjected to surgical intervention, was observed, with the proximal tibia group showing the most pronounced deficits. None of the groups exhibited changes in strength over time. All groups had decreased joint flexion in the treated limb compared to the untreated limb 12-18 months post-surgery. Timed Up and Go performance improved in all groups but remained below average compared to reference values. An association was observed between a lower Timed Up and Go Test and higher Musculoskeletal Tumor Society scores, with the latter being lowest in the proximal tibia group.

Conclusion
The study provides data from comprehensive testing the first year following megaprosthesis surgeries providing knowledge in order to inform and guide patients. Markedly reduced strength in both treated and untreated limbs compared to predicted normal values was observed. The significant deficit in walking capabilities showed clear association to patients' reported outcomes.

#17: Nurse navigation, symptom monitoring and exercise in vulnerable patients with lung cancer: Feasibility of the NAVIGATE intervention

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Abstract
Introduction
We developed the Navigate intervention to improve survival among vulnerable lung cancer patient. In this intervention-only study, we examined feasibility in terms of recruitment, retention, attendance, adherence, and acceptability to specify adjustments to study procedures and intervention components prior to a randomized trial.

Methods
The Navigate intervention includes nurse navigation, patient-reported outcomes, and physical exercise. Patients >18 years old, diagnosed with non-small cell lung cancer at any stage, with performance status <2, eligible for cancer treatment and vulnerable according to a screening instrument were included. The recruitment goal of eligible patients was 40% while the retention goal was 85%. The predefi ned cut-off s for sufficient attendance and adherence were >75%. Acceptability was evaluated by semi-structured interviews with participants, nurse navigators, and physiotherapists.

Results
Seventeen (56%) out of 30 screened patients were considered vulnerable and eligible for the study, 14 (82%) accepted participation, and 3 (21%) were subsequently excluded due to ineligibility, leaving 11

patients. Four patients dropped out (36%) and four patients died (36%) during follow-up and 3 (27%) were retained. All 11 patients participated in nurse sessions (mean 16, range 1–36) with 88% attendance and dialogue tools being applied in 68% of sessions. Ninety-one percent of patients responded to PROs (mean of 9 PROs, range 1-24) with 76% of the PRO questionnaires used (attendance) and 100% adherence (completion of all questions in PRO questionnaires), and 55% participated in exercise sessions with 58% attendance and 85% adherence. We identified important barriers primarily related to transportation, but overall acceptability was high.

Conclusions
The Navigate intervention was feasible with high participation, acceptability and satisfactory adherence. Retention and exercise attendance were low, which resulted in adjustments.

#18: Intraluminal Application of Fosfomycin and Metronidazole in Patients with Right-Sided Colon Cancer: Results from the MEFO Trial

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Abstract

Introduction
Biofilms with Fusobacterium nucleatum (Fn) are overrepresented in patients with right-sided colon cancer (CC) and are associated with poor survival. Antibiotic treatment reduced tumor volume in a mouse model and adenoma burden in patients with FAP. This study aimed to investigate the eff ect on the tumor microenvironment and safety of preoperative fosfomycin and metronidazol application in patients with right-sided CC.

Materials and methods
Patients with right-sided CC who were planned for resection at Zealand University Hospital and Herlev Hospital were eligible for inclusion in the trial. The intervention was an intraluminal antibiotic spray application containing 800 mg fosfomycin and 200 mg metronidazole covering the mucosa of the right hemicolon. Primary outcomes were changes in mucosa-associated bacterial biomass and composition (FISH and 16S rDNA sequencing). Secondary outcomes were changes in immune cell density (CD3 and CD8) and safety evaluation (Common Terminology Criteria for Adverse Events (CTCAE)). Samples were collected pre- and post-intervention from the normal mucosa (M), the tumor periphery (TP), and the tumor center (TC).

Results
10 patients were included. Only patients with a high baseline level of bacterial biomass (> 0.05‰) had a significant reduction at the TP (3‰ vs 0‰). The microbial composition significantly diff
ered after the intervention across tissue localisations, with no reduction in richness or diversity. In the TC, a reduction of Fn was shown (15 vs 0%) with an increase of Lactobacillales (0 vs 3%) and CD8/CD3 ratio (0.3 vs 0.8 CD8/CD3). No patients had CTCAE grade 3-5.

Conclusions
Intraluminal antibiotic application reduced bacterial biomass in patients with a high baseline level and no serious adverse patient outcomes were observed. A reduction in Fn abundance and an increase in Lactobacillales suggests intraluminal application of antibiotics as a safe way to modulate the microbiome in patients with right-sided CC.

#19: Clinical pathway and technique of Pressurized IntraThoracic Aerosol Chemotherapy (PITAC) directed therapy

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Abstract
Introduction
Pressurized IntraThoracic Aerosol Chemotherapy (PITAC) is a minimally invasive therapy for patients with malignant pleural effusion (MPE) and/or pleural metastasis (PLM). PITAC is based on Pressurized IntraPeritoneal Aerosol Chemotherapy (PIPAC), which has been proven to be a lenient, eff ective, and safe palliative treatment for patients with peritoneal metastasis. There is no consensus on PITAC indications, techniques, or methods of response evaluation, and prospective clinical data are scarce. We defi ned a clinical pathway, provided a detailed description of the procedure and began recruiting patients for the first PITAC phase I trial (PITAC-OPC5) in September 2023.

Materials and methods
Presentation of clinical pathway and technique of PITAC directed therapy in patients with MPE/PLM. The method used in PITAC-OPC5 is based on the available literature, previously performed PITAC in Denmark from 2018-2021, and the experience from PIPAC including the safety checklist tested during the PIPAC-OPC1 study.

Results
Potential patients for the phase I PITAC study were identified at the MDT conference and their clinical pathway included CT scans, lung function, lung ultrasound, and close follow up after treatment. PITAC was performed in prone position with double lung ventilation and using a 5 and 12 mm trochar. MPE was evacuated, PLM scored using a specified list, and biopsies were taken for analysis of response according to the Thoracic Regression Grade Score (TRGS). Cisplatin and Doxorubicin were nebulized in doses equivalent to PIPAC therapy. Postoperative monitoring included lung function test and chest ultrasound. Preliminary data on time consumption, technique, and complications indicates that PITAC is feasible, safe and repeatable.

Conclusion
Based on careful patient selection, supported by a new patient pathway, detailed procedure description and check list preliminary data indicates, that PITAC may be safely performed.

#20: Supervised aerobic and resistance training during neoadjuvant chemotherapy and tumour response in patients with breast cancer (Neo-train): results from a randomized controlled trial

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Abstract

Introduction

Evidence shows that exercise during neoadjuvant chemotherapy (NACT) benefits both physical and mental health in patients with breast cancer. Pre-clinical studies suggest positive changes of aerobic exercise on the tumour microenvironment with improved chemotherapy delivery, but evidence in human patients is limited. We hypothesized that a supervised exercise intervention during NACT might improve tumour response in patients with breast cancer.

Material and methods

Neo-train was a two arm, parallel randomized controlled trial recruiting patients with breast cancer starting standard NACT at the Department of Oncology, Zealand University Hospital between June 2021 and August 2023. Participants were randomized to either a usual care control group or the exercise group receiving supervised high-intensity interval training and progressive resistance training three times weekly during NACT at five locations across Region Zealand, and screening-based advice to seek counselling in case of moderate-severe psychological distress. The primary outcome was tumour response by magnetic resonance imaging. Secondary outcomes included Residual Cancer Burden, chemotherapy completion, hospital admissions, tumour infiltrating lymphocytes, tumour vascularity, circulating tumour DNA,

metabolic and inflammatory markers, physical fitness, muscle strength, body composition, level of physical activity, health-related quality of life, anxiety and depression.

Results
A total of 102 participants (N=50 in exercise group, N=52 in usual care group) were included (51% of invited patients). Data analysis is ongoing and results will be presented at the conference.

Conclusions
The transparent documentation of the exercise intervention and insight in underlying biological mechanisms will be beneficial for the design of future trials investigating effects of exercise on clinical outcomes.

3. Emerging treatments #21-29

#21: Time to modernise clinical trial inclusion criteria? The impact of NCCN-IPI as a selection tool for identifying trial-eligible population with newly diagnosed diff use large B-cell lymphoma

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Abstract
Introduction
The standard fi rst-line treatment (R-CHOP) in diff use large B-cell lymphoma (DLBCL) has been unchanged over 20 years. Several fi rst-line randomised controlled trials challenge its effi cacy, including the ongoing EPCORE DLBCL-2 trial, which excludes patients with low-risk International Prognostic Index (IPI 0-1). Although a more accurate, widely validated model (NCCN-IPI) has been proposed, it has not been part of the trial selection criteria. We analysed the impact of patient selection for clinical trials based on NCCN-IPI instead of IPI using trial criteria according to the EPCORE DLBCL-2 trial.

Methods
Newly diagnosed patients with DLBCL (age 18-79 years) identifi ed in the Danish Lymphoma Registry (LYFO) were included in the study. Patients with poor performance status, treated with dose-reduced therapies, CNS involvement, previous malignancy and inadequate hematologic, renal, and hepatic function were excluded.

Results
Of 5,204 patients identifi ed in LYFO, 2,868 were trial-eligible (55.0%). However, if patients with low-risk IPI were excluded (940 patients, 32.8%), only 1,928 (37.0%) would be candidates for a clinical trial. In contrast, more patients (2,525, 48.5%) could be included in the analysis if patients with low-risk NCCN-IPI (343, 12.0%) were excluded. Patients with low-risk IPI had inferior 5-year overall survival (91.4% vs 97.5%) and higher incidence of relapsed disease (10.1% vs 4.1%) and deaths (15.6% vs 4.1%) than patients with low-risk NCCN-IPI.

Conclusions
We found that many patients are precluded from clinical trials due to stringent inclusion criteria. If prognostic models (IPI) are used as additional criteria, less than 40% would be trial-eligible. By using NCCN-IPI instead of IPI, more patients potentially benefi ting from experimental treatment could be included. Only a small proportion of patients with excellent prognoses will be excluded, allowing easier implementation of new treatments for the larger DLBCL population.

#22: Use of Complementary and Alternative Medicines in patients with Gastrointestinal Symptoms after Treatment of Cancer in the Pelvic Organs

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Abstract

Introduction
Use of Complementary and Alternative Medicine is increasing in patients with cancer. There is limited data on CAM intake in patients with late adverse effects following cancer treatment. We aimed to identify the prevalence and type of CAM use, and to investigate the association with sequlae in pelvic cancer survivors.

Methods
Cancer survivors referred to our tertiary late adverse effects clinic were invited to participate in a cross-sectional questionnaire study at first visit with the dietician. Gastrointestinal symptoms and impact on quality of life were obtained from the following questionnaires: Gastrointestinal Symptom Rating Scale-Irritable Bowel Syndrome (GSRS-IBS), the Low Anterior Resection Syndrome Score (LARS), self-rated bowel function, and the EuroQol five-dimensional five-level (EQ-5D-5L) questionnaire. Patients were asked to identify use of CAM before treatment at the clinic.

Results
A total of 183 patients (128 (70%) women) were included, with a mean age of 62 (60-64) years. Patients had been treated for colon-, rectal-, anal, cervical- and ovarian cancer. Most patients (n=110) had been treated for colorectal cancer. A total of 139 (76%) were regular CAM users, with 55% using at least one or two supplements. The most used CAMs were vitamin and mineral supplements (48%) and calcium with vitamin D (34%). More than half (56%) used supplements like fish oil, psyllium and probiotics, while 41 (22%) used practices like acupuncture and zone therapy. Usage of non-vitamin/non-mineral supplements and/or medical practices to alleviate bowel symptoms were 65 (42%) and 37 (93%), respectively. The use of CAMs was more common among women compared to men (84% vs 56%), P=0.001), and the intake was most frequent among patients older than 65 years ($p<0.05$).

Conclusions
76% of patients used CAM. Vitamins and minerals, calcium, vitamin D, fish oil, psyllium and acupuncture were the most used CAM to alleviate adverse effects to cancer treatment.

#23: Development of national AI models for automated target delineation in breast cancer radiotherapy for the 'DBCG DL Nation' prospective randomized trial

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Abstract
Introduction
In breast cancer (BC) radiotherapy (RT), delineation of the target structures for irradiation, i.e. breast and regional nodes, is performed manually in CT scans. The delineation task is both time consuming and prone to variations among clinicians. Artificial intelligence (AI) is well suited as an aid for delineation tasks. The Danish Breast Cancer Group (DBCG) will investigate the clinical impact of AI-assisted delineation in a national prospective randomized trial. This study aimed to develop the AI models to be used in the trial.

Materials and methods
In a national DBCG delineation workshop, 21 experts from all seven Danish RT centers spent more than 300 workhours to create a high-quality ground truth data set for 315 BC patients. The generated data were used to train and test AI models to predict internal mammary nodes (IMN) and axillary nodal levels (LN). AI model predictions were quantitatively compared with ground truth (expert) delineations using the Dice Similarity Coefficient (DSC, ranging from 0~no overlap to 1~perfect match). In a qualitative evaluation, 14 experts assessed AI model predictions and expert delineations in a blinded comparison. The assessment ranked clinical usability on a scale from 1 to 4 (1:No corrections needed, 4:Easier to start from scratch).

Results
The AI models achieved a median DSC=0.7 for IMN and DSC=0.8 for LN.In the qualitative evaluation, AI model predictions achieved high scores comparable with expert delineations, with 36% of AI model predictions scoring 1 compared to 34% of expert delineations. The AI model predictions had fewer low scores, with 14% scoring 3 or 4, compared to 25% for expert delineations.

Conclusion
AI models for automated target delineation in BC RT were developed, performing on par with expert delineators and in some cases exceeding. The models will be implemented nationally in a fi rst-of-its-kind prospective randomized trial ('DBCG DL Nation') comparing AI assisted with manual delineation.

#24: Proton therapy for second primary breast cancer in the contralateral breast

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Abstract
Introduction
Radiotherapy (RT) for a second primary breast cancer (BC) is increasingly common due to high survival rates and incidence of BC. Level 1 evidence shows survival gain from RT of the internal mammary nodes (IMN) in high-risk BC. If a patient has received RT to the contralateral breast, it may be difficult to achieve full coverage of IMN and other medial targets without overlapping with previously irradiated tissue. RT with photons typically uses tangential fields whereas RT with protons uses anterior oblique fields, parallel to the previous photon fields, enabling optimal target coverage with minimal overlap. Danish patients have been referred for proton therapy on an individual basis, if the target coverage criteria set by the Danish Breast Cancer Group (DBCG) not met with photon RT. Here, we present target coverage data on this cohort.

Materials and methods
All patients that were treated proton therapy at Danish Centre for Particle Therapy (DCPT) since 2022 for a second primary BC, who previously received RT to the contralateral breast were included. The DBCG RT guidelines recommend that 98% of the breast or chest wall should receive at least 95% of the prescribed dose and that 98% lymph nodes should receive at least 90% of the prescribed dose.

Results
31 patients, previous RT between 2001 and 2023, were identified. 23 patients received coverage of the targets according to DBCG guidelines. For the remaining 8 patients, V95% for breast/chest wall ranged between 73.8% to 97.3% (median, 92.6%). For only two of these patients, a compromise was made on IMN (V90% were 69.3% and 82.7%, respectively).

Conclusions
The majority of patients met the DBCG target constraints. Based on these data, the DBCG RT Committee plans a national prospective cohort study to provide optimal RT for previously irradiated BC patients, who otherwise could not be adequately irradiated.

#25: Elevated cobalt levels in metal-on-polyethylene knee megaprostheses: a prospective 1-year cohort study of 56 patients with hip and knee megaprostheses

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Abstract
Introduction
Concerns have emerged regarding elevated levels of cobalt and chromium in patients with metal-on-metal megaprostheses. This prospective study aims to identify systemic cobalt and chromium levels in metal-on-polyethylene knee and hip megaprostheses and their associations with other factors.

Methods
56 patients underwent knee or hip megaprosthesis surgery at 2 sarcoma centers. Serum cobalt and chromium levels were measured preoperatively and thrice within the first year using Inductively Coupled Plasma Mass Spectrometry.

Results
A statistically significant difference in serum cobalt levels (1.4 ppb; 95% confidence interval [CI] 0.0–3.3) was observed 1 year after knee megaprosthesis surgery compared with preoperative levels. In contrast no difference in chromium levels was observed after 1 year compared with preoperative levels (0.05 ppb; CI 0.0–0.8). An association between younger age, higher eGFR and increased cobalt levels were observed. No significant correlations were found between ion levels and resection length or the number of modular connections.

Conclusion
We found elevated serum ion levels in metal-on-polyethylene knee megaprostheses in contrast to metal-on-polyethylene hip megaprostheses. Furthermore, a positive correlation between cobalt and chromium levels, and between cobalt and eGFR were identified, along with a negative correlation between cobalt and age. This study highlights the importance of monitoring systemic cobalt and chromium levels in patients with megaprostheses.

#26: Feasibility of Weekly Cisplatin and Radiotherapy for Localized Anal Cancer – A Danish Anal Cancer Group report

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Abstract
Background
Chemoradiotherapy (CRT) with fl uorouracil and mitomycin is the standard treatment for squamous cell carcinomas of the anus (SCCA). Compliance with treatment is crucial for achieving locoregional control, but the treatment related acute toxicity often results in treatment breaks. Although weekly cisplatin is a well-established treatment for squamous cell carcinomas in other sites, it has not been evaluated in SCCA.

Purpose
To investigate if radiotherapy (RT) with weekly cisplatin is a feasible treatment option for SCCA and to report the associated acute toxicity.

Methods
We identified patients with SCCA treated with curative RT and weekly cisplatin (40 mg/m2) from 1998-2020. Data was obtained from medical records (n=116) and a subset (n=51) were included in a Danish observational study comprising physician-assessed toxicity (NCI-CTCAE 4.0), patient-reported outcomes (EORTC-QLQ-C30+CR29) at baseline, mid-therapy, end of therapy and 2-4 weeks post-treatment (n=51). Disease free survival (DFS) and overall survival (OS) were calculated using the Kaplan-Meier method.

Results
A total of 116 patients were included. T-stage distribution was T1: 4%, T2: 71%, T3: 17%, T4: 8% with 47% having N+ disease. Radiotherapy doses to the tumor ranged from 53.75Gy-64Gy. The mean cumulative cisplatin dose was 307.5 mg and the median overall treatment time was 43 days. Complete response was seen in 89% of patients within 6 months after CRT. The median follow-up time was 4.5 years with 5-year DFS and OS rates of 77.7% (95%CI 68.7-84.5%) and 86.4% (95%CI 78.3-91.7%), respectively. Hospitalization was required in 20% of cases, 2.6% due to febrile neutropenia. Hematologic toxicity was low with 13.7% grade 3 and 3.9% grade 4. Anal pain, skin, gastrointestinal and urogenital toxicity were mild.

Conclusion
Our results show that RT combined with weekly cisplatin is an effective and safe treatment option in relation to outcome and acute toxicity.

#27: Real-life status on efficacy and outcome after treatment with pembrolizumab in patients with advanced anal cancer in Denmark

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Abstract
Background
Non-resectable recurrent or metastatic squamous cell carcinoma of the anal canal (SCCA) is a rare disease and there is only limited high-quality data available regarding the optimal treatment. Published data from phase II studies suggest anti-tumour effect of the immune check-point inhibitor Pembrolizumab. This study aims to assess the efficacy of Pembrolizumab in a national Danish real-world cohort of patients.

Methods
We conducted a retrospective study including all Danish patients treated with Pembrolizumab for advanced/metastatic SCCA outside of clinical trials in the period September 2018 to September 2023.

Results
Thirty-seven patients were included in the study. The majority of patients were female (N=24), and had p16 positive tumours (N=27). Four patients were treated with Pembrolizumab in 1st line, 28 in 2nd line and 5 in 3rd or later line. About half (N=17) were 67 years or older. Objective response rate (ORR) was 10.8%, including one complete response. Taking into account patients with stable disease as best response, clinical benefit rate was 45.9%. Two ongoing, durable responses > 24 months without progression were observed. Median progression-free survival (PFS) was 4 months (95% CI 2.6 - 5.5 months), while median overall survival (OS) was 10.5 months (95% CI 7.3 - 15.7 months). A median of 4 cycles of Pembrolizumab was administered (range 1 - 33). Toxicity was manageable, with 2 patients requiring hospitalisation for grade 3 side ef ects. There were no deaths attributed to immunotherapy.

Conclusion
We found Pembrolizumab a viable treatment option for patients with advanced/metastatic SCCA, with estimates for ORR, PFS and OS comparable to the data available from early clinical trials. Complete and durable responses were observed, but studies to identify factors which can improve selection of patients for immunotherapy are warranted.

#28: Proton Minibeam Radiotherapy Drastically Reduces NTCP In Vivo

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Abstract
Proton minibeam radiotherapy (pMBRT) is an advanced form of irradiation modality utilizing (sub-)millimeter dose slices. It aims to increase the therapeutic window and has been identified as a technique that could supplement conventional proton therapy. This study reports on the commissioning of a minibeam multi-slit collimator (MSC) and the initial in-vivo assessment of pMBRT's efficacy in reducing normal tissue toxicity.

We constructed a pMBRT collimator, a static MSC, optimized using Geant4 Monte Carlo simulations to achieve a uniform dose distribution in the planning target volume (PTV) and a sharp lateral dose contrast at the entrance, while minimizing nuclear activation and neutron production. Treatment plans were generated using Varian ECLIPSE TPS and modified to ensure a homogenous PTV dose upon insertion of the collimator. The PTV spanned from 55 mm to 85 mm in water depth. Normal tissue complication probability (NTCP) was evaluated near surface (2 mm depth), where a dose-response relationship was established using acute skin toxicity for both a conventional proton beam and pMBRT. To avoid ill-defined dose concepts, NTCP at entrance is recorded as a function of (physical) PTV dose for direct comparison. Acute skin toxicity was evaluated in 72 unanesthetized female C3H/HeNRj mice legs over a 22-day post-irradiation period.

pMBRT, when compared to conventional proton therapy, significantly reduced skin toxicities. Even for the higher PTV doses, we did not observe any toxicities above grade 2 for pMBRT.

The study underscores pMBRT's remarkable potential to spare healthy tissue while delivering a homogeneous target dose. These promising results support the broader clinical implementation of pMBRT. Full dose-response curves are needed to establish the grid factor, which may provide a robust metric for future clinical applications.

#29: Enhancing Proton Therapy Through Boron Neutron Capture: Analyzing Artificial Neutron Rich Proton Beams In-Vitro and Microdosimetrically

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Abstract
Introduction
The possibility of benefiting from neutrons generated in proton therapy by BNCT reactions, was first proposed in 2017. Recent collaborative studies conducted at The Danish Centre for Particle Therapy (DCPT) and the University of Wollongong suggested that the strategic placement of a 7 mm tungsten shield in the entrance region of a scanned proton beam could yield sufficient spallation neutrons detectable in a microdosimeter modified with a 10B film. In this “tainted” proton beam, the measured dose average lineal energy (yd) showed an increase from 6.4(5) keV/um to 8.7(4) keV/um (35 % increase). This study extends the microdosimetric measurements with clonogenic cell survival assay to investigate any RBE enhancements from this setup.

Materials and methods
For the in-vitro investigation, we employed V79 cells (Chinese hamster lung fibroblasts). The cells were incubated for 6 hours before irradiation in a medium containing 0.17 mg/ml of 10B-enriched sodium borocaptate (BSH), resulting in a 96 ppm concentration of 10B. Both BSH-exposed and non-exposed cells were irradiated with 4 Gy or 8 Gy. Each biological replicate included eight control flasks (with/without BSH exposure).

Results
The clonogenic cell data obtained showed that cells exposed to 10B enriched BSH induces a shift towards smaller cell colonies. This shift was only observed to a small degree in the control flasks. The survival curve is generated with an approximately 50 cells cut-off value. The choice of this threshold can yield varying RBE values. In the case of this specific threshold, an RBE10% of 1.1 is achieved.

Conclusions
An increased relative biologcal effect is observed in neutron rich protons beams for BSH exposed cells, with an RBE10% of approximately 1.1. The effect is supported by microdosimetric measurements that show a change in the lineal energy spectra, with a yd increase of 35 %.

4. Patient involvement #30-38

#30: Hvad fremmer bæredygtig implementering af beslutningsstøtteværktøjer blandt klinikere? Et kvalitativt studie blandt læger og sygeplejersker i en onkologisk afdeling

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Abstract
Introduktion
Beslutningsstøtteværktøjer er evidensbaserede redskaber designet til at støtte patienter i at træffe informerede valg om deres behandling og til at supplere samtalen mellem patient og kliniker. Studier viser dog, at der er uoverensstemmelse mellem intention og adfærd hos lægerne, når det kommer til bæredygtig brug af beslutningsstøtteværktøjer. Der er ingen studier, der har rapporteret om en vedvarende, vellykket implementering af et beslutningsstøtteværktøj. I en dansk onkologisk afdeling er det lykkes et team af læger og sygeplejersker at fastholde brugen af et beslutningsstøtteværktøj, der blev indført til adjuverende behandling af colorectalpatienter i 2018. Formålet med dette studie er derfor eksplorativt at undersøge deres opfattelse af og motivation for at fastholde brugen.

Materiale og metoder
I foråret 2023 blev der gennemført to fokusgruppeinterviews med henholdsvis læger (n=7) og sygeplejersker (n=4), der arbejdede sammen i par under konsultationen. Data blev kodet med en åbenhed for informanternes oplevelser i en kombineret induktiv og deduktiv proces.

Resultater
Der fremstod to overordnede temaer 1) beslutningsstøtteværktøjet er et pædagogisk værktøj til at inddrage patienten – både strukturelt og visuelt, og 2) beslutningsstøtteværktøjet bidrager til, at patienten er centrum for samtalen. Beslutningsstøtteværktøjet gør, at fokus i samtalen er på patientens præferencer og livssituation, hvilket blev opfattet som den største fremmer og motivation for at anvende beslutningsstøtteværktøjet.

Konklusioner
Studiet viser, at brugen af beslutningsstøtteværktøjet i samtalen med colorectalpatienter om adjuverende behandling har en betydelig positiv indvirkning på lægernes og sygeplejerskernes oplevelse af samtalerne. Gennem to identificerede overordnede temaer demonstrerer studiet, hvordan beslutningsstøtteværktøjet bidrager til bedre samtaler for både patientens opfattelse af egen situation og for lægens praksis

#31: The patient-driven development of a PRO measure for use in routine colorectal cancer care

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Abstract
Introduction
Colorectal cancer care is currently focusing mainly on anticancer treatment and related side-effects. This study aimedto foster the patient-driven development of a core set of person-centered outcome constructs for colorectal cancer. These constructs will serve as the foundation for a person-centered PRO measure for use in routine care.

Materials and methods
Patient perspectives were collected from four distinct sources: 1) A national cross-sectional survey on late effects 5-10 years after colorectal cancer, 2) queries posted on the main page of the Facebook group for people with “Late effects after colorectal cancer”, 3) a virtual workshop involving volunteers from The Danish Bowel Cancer Association, and 4) a 1-day workshop with in-person attendance by individuals living with or after colorectal cancer and their caregivers. These workshops encompassed plenary sessions, group discussions, and voting. Qualitative analysis was conducted on the content to identify a list of core constructs.

Results
Of the 6,989 surveyed, 3,955 (56.6 %) responded. Additionally, 42 responses were received from the Facebook group. In the virtual workshop, 11 participants (10 patients and 1 caregiver) engaged. 10 individuals (7 patients and 3 relatives) attended the inperson session. From these interactions, the following patient-reported outcome constructs were recognized as pivotal within the colorectal cancer care context: self-rated well-being relative to pre-diagnosis, late effects encompassing both psychological and physical aspects, the role of caregivers, identity considerations, support systems, employment and economic impacts, rehabilitation needs, and information provision.

Conclusions
Patients' and caregivers' perception of essential aspects of colorectal cancer care differ from current practices. A list of constructs reflecting their primary needs and priorities has been developed, paving the way for compiling a PRO measure to address these outcomes.

#32: Meningsfuld inddragelse af pårørende – fælles beslutningstagning ved prostatakræft

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Abstract
Indledning
Patienter har tit en pårørende med til konsultationerne på hospitalet. Men de pårørende føler sig ofte ikke meningsfuldt inddraget i beslutningerne, der foretages. Forskning viser, at aktiv inddragelse af pårørende i patientens sygdomsforløb, behandling og pleje, i overensstemmelse med de pårørendes evner og behov, forbedrer den samlede oplevelse for både patienter og pårørende. På trods af dette er de pårørendes rolle i fælles beslutningstagning stadig underbelyst forskningsmæssigt. Dette studie fokuserer på hospitalskonsultationer med prostatakræftramte patienter, hvor der er pårørende til stede og har til formål at udforske pårørendes, patienters, læger og sygeplejerskers opfattelse af pårørendes rolle i beslutningstagning.

Metode
Studiet bygger på kvalitative data fra nov. 2023 – jan. 2024 og indfanger øjeblikke med beslutningstagning vha. en induktiv hermeneutisk-fænomenologisk tilgang til at forstå informanternes levede erfaringer ift. de pårørendes rolle. Fire fokusgruppe interviews (læger, N=5, sygeplejersker, N=6) og 20 semistrukturerede individuelle interviews (patienter, N=10, pårørende, N=10) fordelt ml. erhvervsaktive/pensionister. Feltnoter fra 13 konsultationer udgør grundlag for interviewguides.

Resultater
Interviewene viser, at pårørende spiller en vigtig rolle i konsultationerne. De bliver patientens ambassadør i form af "støtte", "sekretær", "barnepige", "ekstra ører" og "stemme". Men det er samtidigt stressende for den pårørende at få tildelt disse roller, ud over det følelsesmæssige aspekt ved at bekymre sig om situationen. Lægerne og sygeplejerskerne oplever de pårørende, som en værdifuld ressource, men samtidigt også, at de har behov, som også kræver opmærksomhed under konsultationen.

Konklusion
Resultaterne kan hjælpe læger og sygeplejersker i beslutningssamtaler, hvor der er pårørende til stede ved at inddrage de pårørende som en ressource og samtidigt at være opmærksom, at de også har behov og er ramte af at leve med sorgen.

#33: Does the impact of a colostomy on quality of life change with time? - prospective evalutation in rectal cancer patients

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Abstract
Introduction
The number of long-term rectal cancer (RC) survivors is increasing. Curatively intended surgery for RC may involve formation of a permanent colostomy and understanding the impact on patient's quality of life (QoL) is important for shared decision-making. We report findings from a national, multicenter prospective follow-up program after RC surgery, to describe how stoma function and QoL change during the first years after surgery.

Materials and methods
Patients were included from three centers in a systematic screening program for late sequelae using patient-reported outcome measures (PROMs). Inclusion criteria were surgery for RC, formation of a colostomy and completion of PROMs at 3 and 12 months including the Colostomy Impact (CI) Score and EQ-5D-5L. Clinical data were from the Danish Colorectal Cancer Group registry. CI Scores were compared using Wilcoxon matched-pairs signed-rank test, and EQ-5D data using paired ttest.

Results
In total 269 patients (33.5 % females) completed PROMs at 3 and 12 months postoperatively, mean age was 70.6 years (range 21.9-91.5). Median CI Score was 8 (IQR 4-14) at 3 months and 9 at 12 months (IQR 5-14) p=0.18. Compared to 3 months, patients had more problems with smell, leakage, stool consistency and parastomal bulging, but better stoma self-care at 12 months. From 3 months to 12 months 41.7% of the patients stay in the minor CI category. Ten percent experience worsening from minor to major CI whereas 15.8 improve their stoma function from major to minor CI, and 32.5% stay in the major CI category. No differences were found for EQ-5D dimensions or EQ-VAS between 3 and 12 months postoperative. Except slight improvement in EQ-5D mobility both EQ-5D and CI scores were unchanged at 24 and 36 months.

Conclusions
Stoma-related problems persist, but change during the first year after surgery, however this is not reflected in CI Score or generic QoL. Systematic screening should be considered to offer relevant counselling.

#34: Danske kræftpatienters perspektiver på det samlede kræftforløb fra første symptom til opfølgningsforløbet og hverdagslivet med og efter kræft

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Abstract
Introduktion
Patientperspektivet er et vigtigt parameter når kvaliteten af sundhedsvæsenet skal vurderes. Patienternes viden indeholder unik viden om bl.a. sammenhængsproblematikker og spiller også ofte en rolle i forbedringsarbejdet. Kræftens Bekæmpelses Barometerundersøgelser har siden 2011 leveret aktuel og repræsentativ viden om kræftpatienters behov og oplevelser i det samlede kræftforløb, og i 2023 blev der gennemført en ny undersøgelse.

Metode
Barometerundersøgelsen er en national populationsbaseret spørgeskemaundersøgelse, hvor alle førstegangskræftpatienter diagnosticeret i en given periode i Danmark i alderen 30-99 år inviteres til at deltage. Undersøgelsen er todelt og i del 1modtager én gruppe patienter 4-8 mdr. efter diagnosen et spørgeskema om udredning og behandling, og i del 2 modtager en anden gruppe et spørgeskema om opfølgnings- og efterforløbet 2-2,5 år efter diagnosen. I undersøgelsen fra 2023 blev ca. 7.000 kræftpatienter inviteret til hver delundersøgelse; 3.070 patienter besvarede del 1 (svarprocent 45 %) og 3.232 besvarede del 2 (svarprocent 46 %).

Resultater
Overordnet set udtrykker patienterne stor tilfredshed, især med behandlingsforløbet på sygehuset. Men undersøgelsen viser også, at mange kræftpatienter oplever væsentlige fysiske, psykiske og/eller sociale problemer og senfølger, som sundhedsvæsenet ikke i tilstrækkelig grad tager hånd om. Derudover tegner den et billede af et sundhedsvæsen, hvor sektorerne ikke i tilstrækkelig grad arbejder sammen om og med patienterne, men hvor mange patienter oplever at stå med et ansvar, som de mener sundhedsvæsenet burde have haft.

Konklusioner
Resultaterne peger på et behov for et øget patientcentreret fokus, herunder på patienternes individuelle behov, ønsker, præferencer og ressourcer for at sikre høj, ensartet kvalitet for alle kræftpatienter samt for at sikre at kræftpatienter oplever sammenhæng og tryghed i deres forløb og ikke lever med væsentlige senfølger efter sygdom og behandling.

#35: Physician assessed and patient-reported acute radiation-induced diarrhoea in patients with prostate cancer during curative radiotherapy - A prospective Danish multicentre study

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Abstract
Introduction
Acute radiation-induced diarrhoea (RID) is caused by an acute inflammatory reaction of the normal gut mucosa and typically occurs two weeks after start of external beam radiotherapy (EBRT) to carcinomas in the pelvis. The most used validated tools to diagnose RID are the Common Terminology Criteria for Adverse Events (CTCAE) and the Bristol Stool Chart. However, none of them are based on patient-reported measures.
The aim of this study was to identify acute RID in patients with prostate cancer using both physician- and patient-reported methods.

Materials and methods
Thirty-seven patients with newly histopathologically verified prostate adenocarcinoma, who were referred to the Depts. of Oncology in Aalborg or Vejle were consecutively included. Curative EBRT was delivered with intensity modulated (IMRT) and integrated boost technique with 78 Gy to the prostate and 56 Gy to the pelvic lymph nodes over 39 treatment fractions.
Acute RID was assessed according to the CTCAE (vers. 5.0), and the patients reported the daily frequency and stool type according to the Bristol Stool Chart. The patients also noted body weight, the use of antidiarrheal medication and laxatives, and the use of incontinence products.
CTCAE assessments were made at baseline, week 8, week 10, and week 16. The patient-reported stool diary was made daily from week 1-10 and during week 16.

Results
CTCAE assessed acute RID of Grade 0 or Grade 1 in 37/37 patients during and eight weeks after EBRT. The patient-reported outcome was: five patients with acute RID of Grade 3, six patients with Grade 2, and 26 patients with Grade 0 or 1. RID of Grade 2 started at week 2, and RID of Grade 3 at week 4.

Conclusions
CTCAE did only identify acute RID of Grade 1, whereas the patient-reported stool diary noticed Grade 2 or 3 in 1/3 of the patients. Future clinical settings should thus include a patient-reported tool to identify and manage acute RID during EBRT.

#36: Hjemmebehandling og digitale løsninger til patienter med hæmatologisk kræft i Danmark

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Abstract

Introduktion
Patienter med hæmatologisk kræft gennemgår ofte lange og intensive behandlingsforløb med hyppige ambulante konsultationer og lang transporttid til og fra hospitalet. Behandlingen i eller tættere på hjemmet øger patienters mulighed for at opretholde hverdagsaktiviteter, være mere fysisk aktive og få støtte fra familie og venner. Undersøgelser viser høj patienttilfredshed og sikkerhed samt færre omkostninger og genindlæggelser ved hjemmebehandling. Det mangler overblik over, hvilke behandlinger der tilbydes som hjemmebehandling. Formålet var at undersøge omfang af og praksis for hjemmebehandling og digitale løsninger til patienter med hæmatologisk kræft i Danmark.

Materiale og metode
Spørgeskema sendt til de fem hæmatologiske afdelinger i Danmark i november 2023. Data omfatter type af og praksis med hospitalsbehandling, der helt eller delvist udføres i hjemmet af enten patienten selv, pårørende eller sundhedsprofessionelle, og hvilke digitale løsninger som telekonsultationer, apps, hjemmemonitorering eller PRO, der erstatter fysisk fremmøde på hospitalet. Derudover implementering, kriterier, antal patienter, dokumentation og planer for nye tiltag.

Resultater
Data fra fem hæmatologiske afdelinger viser stor variation i forhold til, hvilke behandlinger, der tilbydes som hjemmebehandling i Danmark. Azacitidin og immunglobolin tilbydes på alle afdelinger. Intravenøs kemoterapi, hydrering og antibiotisk behandling på programmerbare CADD-pumper, og brug af elastomerpumper anvendes i forskelligt omfang. Der er forskel på, om patienter oplæres i håndtering af intravenøs adgang og skift af infusionspose. Alle afdelinger tilbyder telefon- og/eller videokonsultation.

Konklusion
Der er forskel på hvilke hjemmebehandlinger, der tilbydes på de hæmatologiske afdelinger, til hvilke patienter, og i hvilket omfang patienten selv håndterer behandlingen. Praksis kan med fordel ensrettes på tværs af landet, så geografi ikke er afgørende for behandlingstilbud.

#37: The Prevalence and Severity of Lymphedema Symptoms across Cancer Diagnoses and the Association with Health-Related Quality of Life, Pain, and Depression

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Abstract
Introduction
Lymphedema is a debilitating late eff ect of cancer treatments. Beyond breast cancer, its prevalence remains understudied. This study examined the prevalence and severity of lymphedema symptoms across cancer diagnoses and explored the association with health-related quality of life (HRQoL), pain, and depression.

Material and methods
This cross-sectional study conducted at the Department of Oncology, Rigshospitalet in April 2021 was part of a broader investigation into cancer-related late eff ects. Here, we present data from patients in follow-up who received an online survey regarding lymphedema symptoms (defi ned as heaviness, swelling, or tightness). Utilized questionnaires were The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ-C30 with lymphedema items from VU34, BR23, and H&N43), The Major Depression Inventory, and The Brief Pain Inventory. Associations were examined via linear regression.

Results
Of 1,901 patients who received the lymphedema questionnaire, 1,296 (68%) responded and were included in the analysis. Most participants had breast cancer (48%), followed by gynecological (16%), head/neck (11%), and testicular cancer (17%). Across cancer diagnoses, one-third (n=397) of the participants reported lymphedema symptoms, of whom 62% (n=245) reported mild and 38% (n=152) reported moderate/severe symptoms. The highest prevalence of symptoms was seen in gynecological cancer (59%), followed by head/neck (41%), breast (21%), and testicular cancer (19%). Participants with moderate/severe lymphedema symptoms reported significantly lower scores for HRQoL (physical, role, cognitive, and emotional functioning scales and global health status) and higher scores for depression and pain compared to those with no or mild symptoms.

Conclusions
Across patients in follow-up at Rigshospitalet, symptoms of lymphedema are highly prevalent and associated with lower HRQOL and higher scores for pain and depression.

#38: Older Migrants' Cancer Rehabilitation: Employed Strategies and Experienced Barriers

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Abstract
Introduction
Ethnic inequality in health is widely established worldwide and within the area of cancer, ethnic disparities persist across the entire cancer trajectory, including screening, time to diagnosis, treatment outcomes, survival rates, and rehabilitation. In Denmark, ethnic minority status is identifi ed as a factor that creates vulnerabilities in cancer rehabilitation especially among older migrants due to low socio-economic status, limited education, health literacy level, language barriers, and cultural diff erences. This study explored older migrants' experiences of their cancer trajectories and the rehabilitation practices that they and their caregivers engaged in. The aim was to identify the patients' and caregivers' rehabilitating resources and needs to inform the future development of targeted rehabilitation interventions.

Material and methods
Qualitative interviews were conducted with 14 patients treated for various cancer types in Denmark. Patients were above 50 years old and originated from countries outside Denmark. Seven caregivers, mainly adult children, were also interviewed. Data were analyzed using thematic analysis.

Results
Patients' rehabilitation resources included a wide range of strategies that were primarily practiced outside the established healthcare system and services. They included various forms of physical activity, dietary changes, psycho-social support, and spiritual coping and were supported in family and other social networks. Barriers to rehabilitation were experienced at different levels. They included structural barriers in the health care system and society in general as well as in interpersonal relationships and collaboration with health care professionals and family and social networks.

Conclusions
The study identifies older migrants' rehabilitation efforts and experienced barriers and sheds light on the dynamics that create ethnic inequality within cancer.

5. Morbidity, late effects & rehabilitation #39-48

#39: Surgical Treatment Algorithm For Breast Cancer Lymphedema: A Systematic Review

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Abstract
Introduction
Technical and supermicrosurgical advancements have revitalized surgical treatments for breast cancer-related lymphedema (BCRL), which previously suff ered from limited success. The effi cacy of lymphovenous anastomosis (LVA), vascularized lymph node transfer (VLNT), and liposuction is still unclear, and selecting appropriate patients for each treatment approach is crucial.The aim of this systematic review is to assess the eff ectiveness of these three surgical options to develop a patient-centered treatment algorithm.

Method
We conducted a search of electronic databases including Medline, Embase, Cochrane Library, Google Scholar, and ClinicalTrials.org. Eligible studies were randomized and non-randomized controlled trials, and observational studies that assessed the outcomes of LVA, VLNT, or liposuction. The primary outcome were changes in arm volume, lymph fl ow, and quality of life. Study selection and data extraction were done by two independent reviewers, followed by a risk of bias assessment.

Results
Out of 16,593 papers reviewed, 73 fulfi lled our criteria. Due to low quality of evidence, and considerable heterogeneity, data was narratively presented. Liposuction is signifi cantly eff ective for non-pitting lymphedema. LVA showed inconsistent results, with a tendency of reduced limb volume and symptomatic relief in mild lymphedema. VLNT demonstrated encouraging results for limb volume reduction and symptom improvement in patients with mild and moderate lymphedema.

Conclusion
By conducting this review, we developed a patient-centered treatment algorithm. Liposuction is eff ective for treating non-pitting lymphedema. LVA and VLNT might be effective when targeted for the appropriate patient. Well-conducted high-evidence studies in the fi eld are still lacking to uncover the effi cacy of surgical treatments for BCRL.

#40: High prevalence of erectile dysfunction within the fi rst year after surgery for rectal cancer: a systematic review and meta-analysis

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Abstract

Introduction
Erectile dysfunction is a late complication of surgery for rectal cancer. Intraoperative mechanical nerve damage is a probable cause, but it can also be attributed to radio- and chemotherapy. We aimed to determine the prevalence of erectile dysfunction following rectal cancer surgery within the first year.

Materials and methods
We conducted a systematic review and the last date of search was in August 2023. We included cohort studies reporting on men having surgery for rectal cancer and reporting a prevalence of erectile dysfunction based on validated questionnaires published after 1997. The prevalence of erectile dysfunction was assessed in subgroups of patients who underwent robotic surgery, laparoscopic surgery, and open surgery through forest plots.

Results
Of the 4,105 records identified in the search, we included 74 studies reporting on 9,006 patients operated for rectal cancer. The studies evaluated erectile dysfunction through six validated questionnaires, especially the International Index of Erectile Function (IIEF) version 5 or 15 (84%). The meta-analysis on 22 studies using IIEF (5 or 15) showed that the prevalence of moderate to severe erectile dysfunction was 35% (95% confidence interval 24–47%) within the first year after surgery with very low certainty of evidence. Meta-regression on the prevalence of moderate to severe erectile dysfunction did not show a decrease in erectile dysfunction within the fi rst year postoperatively.

Conclusions
Around every third patient experienced moderate to severe erectile dysfunction within the first year after surgery for rectum cancer, and the prevalence of erectile dysfunction did not improve within the fi rst year after surgery.

#41: Breast induration and irradiated volume in the DBCG HYPO trial: The impact of age, smoking, and boost

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Abstract
Introduction
The phase III Danish Breast Cancer Group (DBCG) HYPO trial randomized patients >40 yrs to whole breast irradiation (WBI) with 40Gy/15fr or 50Gy/25fr after breast conserving surgery. Patients (<50 yrs) and patients with a resection margin <2mm had an additional boost dose to the tumor bed of 10Gy and 16Gy, respectively. The primary end-point was grade 2-3 induration 3 years after radiotherapy.

Materials and methods
Treatment plans were available for all the Danish patients in the trial. Associations between frequency of induration and irradiated breast volume, age, smoking status (current/not), and boost was assessed by logistic regression. Findings were validated in the DBCG Partial Breast Irradiation trial randomizing relatively low-risk patients ≥60 yrs to WBI versus PBI.

Results
Radiotherapy plans from 1,333 patients (median age: 59 yrs) were analyzed with 178 (13%) having grade 2-3 induration. Irradiated breast volume was correlated with induration for patients ≥65 yrs (n=343, 10% versus 22% for small (≤median) versus large (>median) irradiated volumes, p=0.005) but not for patients aged 50-64 yrs (n=792, 11% for both small and large irradiated volumes, p=0.82). Smoking doubled the risk irrespective of irradiated volume and age. These findings were validated in the DBCG PBI study where the median age was 66 yrs. 198 patients in the HYPO cohort had a boost in addition to WBI. The frequency of induration for patients <50 yrs treated with a 10Gy boost (n=156) was 5% versus 21% for small versus large irradiated volumes (p=0.002). An even stronger volume effect was indicated for the few (n=42) 16Gy boost-patients.

Conclusions
A correlation between irradiated volume and induration was seen in patients ≥65 yrs, whereas no such relationship was found for the age group 50-64 yrs. Smoking doubled the risk of induration. All patients <50 yrs had an additional boost, and a dose-volume relation was found due to the higher breast doses in this patient group.

#42: Fatigue, pain and insomnia in cancer survivors and associations with sociodemographic, lifestyle and clinical factors – a SEQUEL study

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Abstract
Introduction
Fatigue, pain and insomnia are some of the most common late effects after cancer. These late effects are multifactorial and may be influenced by sociodemographic, lifestyle factors, comorbidity and treatment.

Materials and methods
This study is a secondary analysis of data from the nationwide SEQUEL cohort of n=39,374 Danish cancer survivors with information on sociodemographic, clinical, lifestyle data and patient-reported outcomes obtained from national registers, clinical cancer databases and a national cross-sectional questionnaire. Pain, fatigue and insomnia were assessed using the EORTC QLQ-C30 questionnaire. The association between patient factors and pain, fatigue and insomnia were calculated as odds ratios (ORs) in logistic regression models with adjustment for relevant confounders. The study is ongoing.

Results
We included 39,374 survivors (19,195 men and 20,179 women) after breast (n=11,833), prostate (n=9619), lung (n=1755), colon (n=4627), rectum cancer (n=2819), melanoma (n=5108) and lymphoma (non-Hodgkin and Hodgkin) (n=3613) diagnosed between 2010-2019. The median age at diagnosis were 64 years. In all, 7757 (21%) survivors reported severe fatigue, 10,774 (29%) severe pain and 6496 (17%) severe insomnia. We found statistically significantly higher ORs for severe fatigue, pain and insomnia for women vs men (OR=1.46, OR=1.62, OR=2.11, respectively), short vs long education (OR=2.01, OR=2.09, OR=1.70, respectively), ≥2 vs 0 Charlson Comorbidity Score (OR=3.47, OR=2.46, OR=1.88, respectively), current vs former smoking (OR=1.48, OR=1.35, OR=1.20, respectively) and obese vs a normal range BMI (OR=1.92, OR=2.21, OR=1.32, respectively). Statistical analyses are ongoing.

Conclusions
The identification of specific patient characteristics for cancer survivors at higher risk of severe fatigue, pain and insomnia can help inform clinicians of who the most vulnerable survivors are and offer guidance for targeted follow-up in cancer survivorship.

#43: Mapping patients with postmenopausal non-metastatic breast cancer symptoms and clinicians insight

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Abstract
Introduction
Patients with postmenopausal non-metastatic breast cancer treated with aromatase inhibitors have experienced an improved quality of life over the past decades. Thus, there is a need for understanding the patient's symptom experience. This study aims to identify how symptoms are identified from the patient's perspective and the clinician's insight.

Materials and methods
A multimethod exploratory study with the following phases: 1) overview of patient-reported symptoms (systematic review, semi-structured patient interviews & medical journal audit) and 2) outline of the clinicians' symptom information (summary of pharmacological products, patient pamphlet, oncological & endocrine national/international guidelines & focus group interview with clinicians). Symptoms were defined according to the National Institutes of Health National Cancer Institute definition and grouped by using the European Organization for Research and Treatment of Cancer Quality of Life C30 (EORTC QLQ C30) questionnaire domains.

Results
7 new domains and 14 EORTC QLQ C30 domains (5 function and 8 symptoms) were explored. The systematic literature review examined 5 new domains: menopausal symptoms, sex-related symptoms, body alteration, and gastrointestinal & eye-related symptoms. The semi-structured patient interviews (n=16) explored 2 new domains: skin-related symptoms & mouth-related symptoms. The summary of pharmacological products and medical leaflets covered 18 domains. The Danish patient pamphlet covered 8 domains. Only one international oncological guideline addressed 2 domains. No additional domains were explored via the medical journal audit (n=23) or
in the outline of the clinicians' symptom information.

Conclusions
Our study showed that patients with early breast cancer in maintenance therapy with an aromatase inhibitor are suffering from various symptoms. Furthermore, a gap between the patient's perceptions and the clinician's insight of symptoms were explored.

#44: Weight Changes and Lymphedema among High-Risk Women Treated for Breast Cancer with Axillary Dissection. Secondary Analyses of Data from the LYCA Randomized Controlled Trial

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Abstract
Introduction
Risk factors for breast cancer-related arm lymphedema (BCRaL) include extensive surgery, adjuvant treatment and higher BMI. However, whether the change in body weight in the time after diagnosis is associated with an increased risk of BCRaL is scarcely examined. In women where treatment included axillary lymph node dissection and radiotherapy, we aimed to examine the association between BMI at time of surgery and development of BCRL 1-year after surgery. Further, we examined the association between weight change and development of BCRaL 1 and 3.5 years after surgery.

Materials and methods
The current study is an exploratory evaluation of data from a randomized controlled trial testing the effect of progressive resistance training in the first post-operative year. We used data from 130 women who were followed prospectively from the time of surgery and up until 3.5 years. Measurements of BCRaL included arm volume by water displacement, self-reported BCRaL symptoms, and clinical examination. Linear and logistic regression models were used to evaluate the association, controlling for potential demographic or clinical confounders and predictors.

Results
We found no association between BCRL and BMI at the time of surgery. At 1 year after surgery there was no significant change in body weight, although from 1 year to 3,5 years mean body weight increased significantly from 73.5kg (standard deviation (sd) 12.2) to 75.1kg (sd 12.5). Women who presented with a weight gain of 5% or more one year after surgery had higher odds for BCRaL (OR 3.66, CI95% [1.02; 13.13]) when a composite measure for BCRaL was used, but with only self-report data available at 3.5 years, this association could not be found.

Conclusion
Thus, we found no association between baseline BMI and lymphedema risk in this group of high-risk women. However, our fi ndings cautiously suggest that there may be an association between weight gain and lymphedema development in the long term.

#45: Psychosocial challenges after treatment for colorectal and anal cancer

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Abstract
Introduction
Receiving a diagnosis of colorectal or anal cancer can profoundly impact an individual's perception of life. It can significantly affect daily functioning due to changes in work ability, treatment-related sequelae, and the psychological distress that often accompanies a cancer diagnosis. However, there is limited research exploring the psychosocial challenges faced by patients following treatment for colorectal or anal cancer. This study aims to identify the relevant psychosocial problems experienced by patients in our population.

Methods
This prospective descriptive study involved patients treated for colorectal or anal cancer, all of whom were evaluated at our Sequelae Center—an available resource for all post-treatment patients. During consultations at the Sequelae Center, we document the specific problems discussed and addressed with our patients. Patients eligible for this study were identified from these records.

Results
A total of 473 patients after surgical treatment for colorectal or anal cancer were evaluated at our center, with 92 patients experiencing psychosocial issues discussed during consultations. We observed that 32% of the 92 patients reported nonspecific complaints, 31% experienced fatigue or difficulties with sleep, 25% struggled with post-treatment life adjustments, and 20% wrestled with existential inquiries, notably pondering about “why did I get cancer?” Additionally, 12% encountered work-related challenges, with many unable to return to full-time employment. Fewer patients reported signifi cant issues with bowel function impacting their quality of life or fear of cancer recurrence.

Conclusion
Our findings indicate that patients undergoing treatment for colorectal and anal cancer commonly experience various psychosocial challenges. Fatigue, diffi culties in adjusting to daily life post-treatment, existential questions, and work-related issues were among the most prevalent concerns in our cohort.

#46: Network of general late effects in 2488 patients after cancer treatment

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Abstract
Introduction
Late effects such as depression, fatigue, or pain often cooccur, which may necessitate interventions targeting symptom networks. This cross-sectional survey of patients not in active treatment at the Department of Oncology, Rigshospitalet, assessed the prevalence and network of general late effects.

Materials and methods
All patients with access to secure email (e-Boks) received a survey in March 2021, assessing demographic and clinical information as well as potential late eff ects: depression (MDI), fear of recurrence (FCRI-SF), insomnia (ISI), fatigue (MFI), pain (BPI), neuropathy (S-LANSS), cognitive function, dyspnea, and gastrointestinal symptoms (all EORTC-QLQ-C30). The prevalence of clinically relevant symptoms was estimated using cut-off scores. Network analyses with multiple imputation estimated partial correlation networks among symptoms and centrality indices in models for all patients, separately for each cancer type, and for different times since diagnosis.

Results
We invited 8728 patients and received scoreable responses from 3348 (40%), 2488 of whom were not in active treatment. Although the most prevalent symptom was pain (reported at clinically relevant levels by 42%), network analysis identified depression as the most central symptom, i.e., the one with the most frequent and strongest cumulative associations with other symptoms. Strong to moderate partial correlations were found between pain and neuropathy (r = 0.49), fatigue and insomnia (r = 0.35), and depression and cognitive function (r = 0.32). Networks adjusted for clinical and demographic factors, run for time since diagnosis or cancer type (except testicular cancer) were similar, with depression or fatigue as the most central symptoms.

Conclusions
General late effects are highly prevalent and significantly associated. Although not the most frequent in our sample, depression and fatigue may be central targets for interventions addressing cooccurring and interrelated symptoms.

#47: Objectively measured prevalence of lymphedema among 336 men with prostate cancer

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Abstract

Background
Mainstay treatments for prostate cancer (PCa) include surgery and radiotherapy which are known to impair the lymphatic system and increase the risk of lower limb lymphedema (LLL). No study has previously objectively measured the prevalence of LLL among men with prostate cancer. Aim: To investigate the prevalence of LLL among men with PCa using objective measurement and patient-reported outcomes (PROs) and understand its impact on activities of daily living (ADL). Materials and

Methods
This study included patients attending follow-up visits at the Department of Urology, Rigshospitalet, between Nov 2022 and Jan 2023. All patients were invited to an in-person visit to complete PROs and undergo measurements of extracellular fluid with bioimpedance spectroscopy (BIS). LLL prevalence was defi ned as a lymphedema-index >7 on BIS with concurrent symptoms of LLL (defi ned as a little, quite a bit, or very much swelling, heaviness, or tightness in the legs or genital area, measured by the vulva cancer-specific subscale EORTC QLQ – VU34). The impact of LLL on ADL was assessed using the Lymphoedema Genito-urinary Cancer Questionnaire.

Results
To date, a total of 336 men have participated, with a recruitment rate of 47%, (mean age 72 (8) years) who were 6 (11) years post-PCa diagnosis. Participants were, on average, 2.7 years younger than non-participants. LLL prevalence was 18%. Prevalence rates varied among treatment groups: radiation therapy 26%, prostatectomy 18%, watchful waiting 14%. Among men with LLL, 59% reported that symptoms affected their physical function or clothing options, while 80% had not received advice or treatment for LLL symptoms, and 79% expressed a desire for more information about LLL.

Conclusion
These data are the first to indicate that LLL is a significant yet underrecognized problem for men with PCa and emphasize the need for prospective studies to understand causality between treatment for PCa and development of LLL.

#48: Late gynecologic toxicity after radiotherapy for anal cancer

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Abstract
Introduction
Female patients with anal cancer (AC) treated with radiotherapy (RT) are at risk of gynecological morbidity and sexual dysfunction. We prospectively collected gynecological outcomes using Common Terminology Criteria for Adverse Events (CTCAE) and patient reported outcomes (PRO) (EORTC-CX24).

Materials and methods
Patients with AC treated with standard RT were included in the DACG I trial. CTCAE and PRO were prospectively collected at baseline (0Y), 1 year (1Y) and 3 years (3Y) after RT. We report sexual activeness, vaginal irritation/tenderness, and abnormal vaginal bleeding according to EORTC-CX24. Vaginal pain, vaginal dryness and vaginal hemorrhage were reported via CTCAE. Wilcoxon signed rank test was used for comparison and Kappa interrater agreement was used for CTCAE vs. PRO comparison of vaginal irritation vs. pain and vaginal bleeding vs. hemorrhage

Results
214 patients (mean age 63 years) were included. PRO completion varied from 72 to 80% and CTCAE from 70 to 92%. At 0Y, 72% reported they were not sexually active, which was 77% at 1Y and 74% at 3Y. Vaginal irritation/tenderness “3- quite a bit” or “4- very much was reported by 8.8% at 0Y versus 13.5% and 12.2% at 1Y and 3Y. For abnormal bleeding corresponding rates were 2.3%, 1.2% and 0%.
According to the CTCAE ≥2 at 0Y, 1Y and 3Y, vaginal dryness was reported for 5.2%, 10% and 13.4%, pain for 1%, 4.7% and 2.7% and hemorrhage 0%, 1.2% and 0%.
Both vaginal irritation/tenderness and vaginal pain increased significantly from 0Y to 1Y, p=0.01 and 0.009, respectively, with no significant change from 1Y to 3Y.
Interrater agreement for vaginal irritation/pain was moderate 61-77%, for bleeding/hemorrhage it was strong 86-94%.

Conclusions
Moderate to severe vaginal symptoms persisted in up to 13% 3 years after RT for AC. Strategies for intervention and relation to RT-dose for Normal Tissue Complication Probability modelling should be explored.

6. Palliation & psychosocial support #49-58

#49: Protective Buffering in Families With Cancer – An Integrative Review

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Abstract
Introduction
When cancer occurs, the whole family is affected. Cancer patients and their family caregivers often experience depression, anxiety, and reduced quality of life. Open communication aids the family to cope with the disease. However, many families with cancer find it difficult to communicate openly during the cancer trajectory. The aim was to explore how nurses can alleviate protective buffering between adult patients with cancer and their adult family caregivers.

Materials and methods
An integrative review was conducted. Databases were searched for primary research articles published between January 2010-April 2022. Only research conducted in oncology, hematology, or multiple settings including oncology and/or hematology was included. The analysis and synthesis followed the constant comparison method.

Results
Out of 7,073 screened references, 22 articles, comparing 19 qualitative and three quantitative studies were included. Three themes emerged: (a) family coping, (b) an isolating journey, and (c) the nurse's role. Few families openly discussed their experiences throughout the cancer trajectory, and withholding feelings and concerns due to the protection of family members – a phenomenon termed "protective buffering" – and oneself. A factor that hindered the nurses' attempt to alleviate protective buffering was that family caregivers felt excluded in consultations and group interventions. Family caregivers experienced nurses paying limited attention to their experiences and needs.

Conclusions
Patients and families feel isolated when there is a lack of communication. When nurses involved and supported family caregivers, coping in families with cancer was facilitated, alleviating protective buffering. Psychosocial interventions can have a beneficial effect on communication in families with cancer. Further research and development of psychosocial interventions that focus on the whole family is needed.

#50: Experiences with End-Of-Life (EOL) for Patients with Pre-Existing Severe Mental Disorders (SMD) – An Interview Study

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Abstract
Introduction
The end-of-life (EOL) period causes suff ering for patients and their relatives. For patients with severe mental disorder (SMD) complex psychosocial challenges are likely to add to the demanding situation. The aim of this study was to investigate patients', relatives', General Practitioners' (GPs) and Specialised Palliative Care (SPC) professionals' experiences with EOL trajectories.

Methods
The study consisted of semi-structured interviews with six patients, their relatives, GPs, and SPC professionals in palliative teams or in hospices in Central Region Denmark. A total of 20 interviews were conducted. A thematic analysis was performed to explore main themes in participant's voices and wishes for EOL.

Results
Six interviews with patients, three interviews with relatives, six interviews with SPC professionals and five interviews with GPs was conducted. Thematic analysis showed four themes that related to each perspective.1) Thoughts about the future 2) Good relations with relatives and HCPs matters3) Both negative and positive changes in psychiatric condition when in the terminal stage existed4) Wish to talk openly about SMD and plan EOL with HCPs HCPs expected the trajectories to be complex when the patient had an SMD. Some HCPs felt they lacked knowledge about SMDs. GPs wanted to give extra service to this patient group and acknowledged the value of a year's long relationship with the patient in EOL care. Relatives talked about the importance of healthy and close relationships with the patient, but also the possible challenges in families, making it difficult for the relative to give the support they want to give.

Conclusions
This study provides insight into patients with SMD's experiences with palliative care and wishes for EOL. Proactivity and collaboration between sectors are needed to provide high-quality EOL care to this patient group.

#51: TelePalliation: Connecting terminal patients with cross-sector care digitally

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Abstract
Introduction
Globally, about 20 million people need palliative care yearly, with cancer, cardiovascular disease, and chronic obstructive pulmonary disease being the primary diagnoses. The Telepalliation program, a digital platform offering various services including chat, video consultations, treatment plan, answers on patient reported outcome (feeling of security, pain and quality of life) was developed collaboratively. This substudy, part of a randomized controlled trial, aims to investigate patient experiences within the TelePal program in palliative care.

Materials and methods
The theoretical framework is Antonovsky's 'sense of coherence' theory. A triangulation of data collection techniques was used: Documents have been studied. Participant-observation was carried out in patients´ homes (n=18 hours). Semi-structured qualitative interviews were carried out with 6 women (ages 44-76) and 4 men (55-60). Of the 10 patients, 6 were diagnosed with cancer and 4 with cardiovascular diseases. The interviews were recorded and analyzed in Nivivo 12.0.

Results
Patients expressed their experiences in terms of feeling secure, finding coherence in their care journey, appreciating improved communication with healthcare professionals across sectors through the TelePal platform, experiencing easier access to the palliative team, and feeling that their partner and family were more involved in difficult conversations with the palliative team via video.

Conclusions
Initial findings indicate that patients enrolled in a Telepalliation program feel secure, experience a streamlined care process, and benefit from integrated care across sectors. Further investigation is required to thoroughly examine the advantages and disadvantages of Telepalliation.

#52: Palliative needs - needs assessment

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Abstract

Introduction
In 2018, the Danish Multidisciplinary Cancer Groups representing the various cancer diagnoses established a committee in order to identify the optimal approach for improvement of early generalist palliative care to cancer patients at the hospitals.

Aim
To investigate the evidence for the hypothesis that 'early palliative care needs assessment followed by palliative care' improves quality of life, reduces symptom burden and/or increases survival from the

diagnosis of advanced cancer. Further, if evidence was found, did it indicate the timing of assessment of palliative care needs?

Method
Systematic literature searches in the PubMed, EMBASE and CINAHL were performed and identified systematic reviews from 2012 to June 2022. The literature was supplemented with searches of randomized controlled trials from 2021 to Nov. 2022. Based on the literature, recommendations were formulated and the strength [A - D] follows Oxford guidelines.

Results
Of the 2,282 references identified, four systematic reviews (based on 17 unique studies) and seven randomized controlled trials were included. In total 24 unique studies. We found that early palliative care needs assessment followed by palliative care increased quality of life and reduced symptom burden for patients with advanced cancer. No effect was found on survival. In most of the studies patients diagnosed with advanced cancer should undergo palliative care needs assessment in relation to diagnosis of the advanced stage of the cancer and then at regular intervals.

Conclusion
Based on the evidence for positive effects of early palliative care, we recommend that: 1) Patients with advanced cancer should receive early palliative care [A]; 2) At the time patients are diagnosed with advanced cancer they should be systematically assessed for palliative needs [B*]; 3) After patients are diagnosed with advanced cancer they should be continuously and systematically assessed for palliative needs [B*].

#53: A program to improve palliative cancer care guideline implementation: development, acceptability and feasibility

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Abstract
Introduction
The National Guideline for Rehabilitation and Palliative Care in Cancer has not been sufficiently implemented across hospital, municipality and general practice sectors in Denmark. This study aimed to bridge the gap between guidelines and general palliative cancer care by designing an implementation program comprising specific implementation strategies and evaluating acceptability and feasibility of these strategies.

Methods and materials
The study was a participatory action research study. The development of the implementation program was inspired by the Quality Implementation Framework and the implementation strategies were selected based on empirical, theoretical, and pragmatic knowledge and experiences. The evaluation included data triangulation of 17 qualitative interviews with healthcare professionals, observations from 55 meetings, and process data collected during the implementation.

Results
The implementation program included five implementation strategies to create a learning collaborative, build a coalition, conduct educational meetings, cyclical small tests of change and facilitation. Evaluation of healthcare professionals' acceptability and feasibility of the implementation strategies showed key themes to consider in national guidelines implementation across sectors: build a coalition should include decision-makers from each healthcare institution to avoid prolonging the implementation process, create a learning collaborative when initiating the implementation to build networks across healthcare professionals and continue with online meetings to ensure participation, and finally, apply a facilitator who may act as a link between the healthcare sectors to ensure progress.

Conclusions
An implementation program, comprising strategies that consider team composition, networking, and facilitation may be an acceptable and feasible approach to improve guideline implementation across healthcare sectors in general palliative cancer care

#54: Valg af fraktionering ved palliativ strålebehandling af knoglemetastaser – 5 års opfølgning på et dansk hospital

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Abstract
Introduktion
Stråleterapi spiller en vigtig rolle i palliativ behandling. Formålet med nærværende studie er at klarlægge valget af fraktioner (F) ved palliativ strålebehandling af knoglemetastaser og undersøge relationen til både kræftdiagnose, prognose og alder.

Materialer og metoder
Studiet er en retrospektiv opgørelse af patienter, som har modtaget palliativ strålebehandling mod knoglemetastaser i perioden 2018-2022 i Vejle. De forskellige strålebehandlingsregimer (8Gy/1F, 20Gy/4F, 20Gy/5F, 30Gy/10F og 39Gy/13F) er analyseret i forhold til kræftdiagnose, alder og generel overlevelse (OS). OS er analyseret med Kaplan-Meier-statistik

Resultater
I alt er 1385 cases inkluderet, fordelt på seks grupper: lungekræft (32.2%), prostatakæft (31.6%), brystkræft (19.8%), myelomatose (7.2%) og tarmkræft med nedre GI (5.7%) og øvre GI (3.5%).
Behandling med 30Gy/10F blev oftest ordineret ved myelomatose, mens 20Gy/4-5F hyppigst blev benyttet til alle andre diagnosegrupper. Når 8Gy/1F blev benyttet var det oftest ved øvre GI.
Median OS var 1.5 mdr. (95% CI; 1.1-1.9) ved øvre GI, 3.1 mdr. (95% CI; 2.5-3.6) ved lungekræft, 4.5 mdr. (95% CI; 3.7-5.4) ved nedre GI, 8.1 mdr. (95% CI; 6.8-9.4) ved prostatakræft, 11.4 mdr. (95% CI; 9.2-13.6) ved brystkræft og 13.0 mdr. (95% CI; 6.3-19.7) ved myelomatose.
Oftest blev der ordineret 30Gy/10F til patienter i god prognose med lang OS ($p<0.001$). Ældre patienter (≥85 år) fik ofte 8Gy/1F men alder var ikke nogen prognostisk faktor for OS. For patienter med prostatakræft var OS længere hos de patienter, hvor 20Gy/4-5F blev ordineret, sammenlignet med 8Gy/1F. For patienter med øvre og nedre GI kræft, var der ikke nogen sammenhæng mellem prognose og valg af fraktionering.

Konklusioner
Klinikeren er i de fleste tilfælde i stand til at udvælge patienter med dårlig prognose til et kort strålebehandlingsforløb. Fremadrettet ønskes yderligere fokus på enkelt fraktion strålebehandling, som bør tilbydes til patienter med dårlig prognose.

#55: CASEMED. Cancer Patients with pre-existing Severe Mental Disorders: Development and pilot test of a collaborative care model

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Abstract
Background
Cancer patients with pre-existing severe mental disorders (SMD), including moderate to severe depression, bipolar disorder and schizophrenia, have reduced life expectancy and are less likely to get recommended cancer treatment. The aim of this study is to develop and pilot test a collaborative care model, to enhance cancer care.

Methods
Four workshops with a total of five cancer nurses, four oncologists, three psychiatrists, two general practitioners (GPs), one psychologist, and 16 patient representatives were conducted to develop a prototype of the model. Thereafter, a pilot test, with 13 patients was carried out, where continuous adaptations to the prototype were made. The quantitative and qualitative data were analysed focusing on acceptability, feasibility, mechanisms of impact and key uncertainties.

Results
From the qualitative data the following themes emerged, and were included in the final model: Early identification of psychiatric comorbidity, engagement of caregivers and professional resources, education of the healthcare professionals, securing continuity among staff, endorsing a person-centered approach and enhanced collaboration between sectors. The latter was achieved through an online psychiatric multidisciplinary team conference (pMDT) where the patient's GP, a project psychiatrist and the patient's oncologist participated.
Thirteen patients agreed to participate and eight pMDTs were conducted. The pMDT was able to suggest treatment optimisation in 6 out of 8 cases, including changes in prescribed medications (50%), re-referral to psychiatric ward (37%) and supplementary oncological consultants (50%).

Conclusion
This study indicates that the CASEMED cancer care model can be implemented in practice and has a potential to optimize the cancer care for patients with cancer and pre-existing SMD. A larger feasibility study is currently being conducted.

#56: Socioeconomic differences in utilisation of systemic anti-cancer therapy: A nationwide pan-cancer study

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Abstract
Introduction
Socioeconomic differences in the use of systemic anti-cancer therapy (SACT) have previously been reported in Denmark. However, the studies were limited to few cancer sites or a specific geographical region. The aim of this study was to assess the association between the use of SACT and socioeconomic position (SEP) across a wide range of solid tumours in Denmark.

Materials and methods
We included adults ≥25 years diagnosed with breast, brain/CNS, gynaecological, gastrointestinal, head/neck, respiratory, and urological cancers in the period 2007-2017. Data on SACT administered between 2007 and 2018 were retrieved from the Danish National Patient Registry, allowing for all patients to have a follow-up time of at least a year. We defi ned SACT as SKS codes starting with BWHA, BWHB, BWHC, BWHW, and BOHJ. SEP data were retrieved from Statistics Denmark and included educational level at year of diagnosis, income quartile a year prior to diagnosis, ethnicity, and cohabitation status at year of diagnosis. Risk ratios (RR) were estimated using modified Poisson regression.

Results
The cohort included 281,962 patients of which 143,034 (50.7%) received at least one SACT administration. Across cancer sites, a long education and high income were associated with an increased chance of receiving SACT (RR = 1.08, 95% CI: 1.07-1.10 and RR = 1.10, 95% CI: 1.09-1.11). Living alone was associated with a reduced chance of receiving SACT (RR = 0.87, 95% CI: 0.86-0.88). The effects were mostly consistent across cancer sites except for urological cancers showing an inverse effect of education and income and no effect of cohabitation. A non-Danish origin was associated with a reduced chance of receiving SACT for urological and gastrointestinal cancers.

Conclusions
Across cancer sites, we found socioeconomic differences in the use of SACT. The reasons behind these differences and whether they indicate over/undertreatment across social groups warrants further exploration.

#57: Promising results of a resource- and activity-oriented intervention integrating rehabilitation into palliative care in people with advanced cancer. A feasibility study testing outcome measures

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Abstract
Introduction
People with advanced cancer experience challenges regarding physical function, fatigue and occupational balance negatively affecting their quality of life. They express needs for interventions supporting the positive aspects of everyday life instead of focusing on problems. This led to the development of The Balance, Activity and Quality of Life Intervention. This study aims to feasibility test if the selected outcome measures of health-related quality of life including physical function and fatigue and occupational balance can capture any possible changes of the intervention in people with advanced cancer.

Materials and methods
The study was design as a repeated-measurement feasibility study without control group. Twenty-two adults with advanced cancer participated. The intervention is resource- and activity-oriented, interdisciplinary, and integrates rehabilitation into palliative care . It was delivered over a five-day intervention-stay and a two-day follow-up intervention-stay six weeks later at the research clinic of REHPA, The Danish Knowledge Centre for Rehabilitation and Palliative Care. Outcomes were collected using the EORTC QLQ-C30 and the Occupational Balance Questionnaire. Changes over time were analysed using Wilcoxon signed-rank test, and a responder analysis was conducted to investigate clinically relevant changes.

Results
The outcome measure of health-related quality of life captured a statistically significant improvement (p=0.0046) after the five-day intervention stay, with 64% of the participants experiencing clinically relevant improvements. No other statistically significant changes were found.

Conclusions
The Balance, Activity and Quality of Life Intervention may lead to improved quality of life in people with advanced cancer. A resource- and activity-oriented approach may be useful when integrating rehabilitation into palliative care. The results will inform pilot-testing in a municipal setting and later full-scale evaluation.

#58: Differences in palliative care needs between cancer patients and non-cancer patients at the start of specialized palliative care – a nationwide register-based study

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Abstract
Background
Patients with non-cancer disease are less likely to receive specialized palliative care than cancer patients. To be able to provide the best specialized palliative care, it is important to understand palliative care needs of non-cancer patients and whether the type and level of needs diff er from those of cancer patients. Large studies including both cancer and non-cancer patients, using validated needs-assessment-tools, are needed to understand differences in palliative care needs at admittance to specialized palliative care.

Aims
To compare palliative care needs at the start of palliative care for cancer and non-cancer disease.

Methods
This six-year nationwide register-based study included patients from all Danish specialized palliative care services (hospice care, hospital-based palliative care, home-based palliative care or consultation) who completed a need-assessment-questionnaire. Ordinal logistic regression was performed to study the association between diagnosis and needs.

Results
Cancer patients had a higher probability of receiving specialized palliative care. Of the 44,315 palliative care admissions included in this study, 93.3% were on cancer patients. Independent of diagnosis patients experienced on average six needs and high levels of fatigue and impaired physical functioning. Non-cancer patients had significantly higher odds of insomnia, fatigue and impaired emotional functioning, physical functioning, and quality of life whereas cancer patients had higher odds of pain (except for patients with neurological disease).

Conclusions
The higher levels of several symptoms/problems among non-cancer patients compared to cancer patients suggests that referral to specialized palliative care should be improved for non-cancer patients perhaps by improving identification of palliative needs.

7. Clinical epidemiology & database research I #59-67

#59: Separating distant recurrences from second primaries in head and neck squamous cell carcinomas – A DAHANCA group analysis on paired tumor samples

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Abstract
Introduction
Patients with head and neck squamous cell carcinoma (HNSCC) are at high risk of developing secondary primary tumors (SPTs) post-treatment. There is no clinically available method to separate distant metastases from HNSCC from squamous cell SPTs. The distinction is important for prognosis, treatment decisions, and trial outcome evaluation. The study aimed to assess the likelihood of a genetic relationship in paired tumor samples, including non-pulmonary sites.

Materials and Methods
The Danish Head and Neck Cancer database (DAHANCA) and the Danish National Pathology Register were used to identify patients and tumor samples. Inclusion criteria covered patients (2007-2017) with pharyngeal and laryngeal cancer and distant metastases at diagnosis or after primary treatment. Eligible patients had solid biopsies from both the primary HNSCC and the corresponding suspected distant metastases. The tissue pairs underwent targeted next-generation sequencing (NGS) of 22 genes (Ion AmpliSeq Colon and Lung Cancer Research Panel v2), including TP53, supplemented with human papillomavirus (HPV) genotyping.

Results
Of the 55 pairs obtained, 33 were successfully analyzed. The included HNSCC subsites were p16-negative OPSCC (N = 11), p16-positive OPSCC (N = 8), hypopharynx (N = 6), nasopharynx (N = 3), and larynx (N = 5). The biopsies were from lung or pleura (N = 16), liver (N = 7), bone (N = 5), and other (N = 5). A genetic match was found in 23/33 (70 %) patients, primarily with identical TP53 mutations or HPV genotypes. In 10/33 patients (30 %), the genetic relationship was absent, all with lung involvement. In patients with no lung involvement, 8/8 had a match.

Conclusions
One-third of patients with DMs in HNSCC lack a genetic relationship with the primary tumors. The risk of misclassifi cation is most prominent for patients with lung involvement and smoking history.

#60: Time toxicity of systemic anticancer therapy for metastatic lung cancer in routine clinical practice: a nationwide cohort study

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Abstract
Introduction
The concept of time toxicity of cancer treatment, defined as proportion of days with physical contact with the health care system, has been suggested as simple, patient-centered measure useful for shared decision-making.

Materials and methods
A nationwide cohort study of patients with stage IV lung cancer in Denmark who initiated treatment during 2019—2021 and followed for up to one year. The time toxicity following treatment initiation was calculated as the proportion and mean cumulative number of days with physical health care system contacts recorded in Danish registries. The remaining days
without any physical contact were defined as 'home days'. One-year cumulative mortality was also assessed.

Results
We included 4,384 patients with stage IV lung cancer. One year survival was 45% following treatment initiation. Of days alive, the mean cumulative number of days with physical health care contacts was 56 days within one year. The corresponding number of 'home days' was 198. Overall, 22% of days alive, involved physical contact with the healthcare system, broadly similar for patients with non-small cell lung cancer (22%) and small cell lung cancer (24%). For specific regimens, the corresponding proportions were chemotherapy (24%), immunotherapy (21%), immunochemotherapy (21%), and targeted therapy (16%).

Conclusion
More than 1 in 5 days after initiation of systemic treatment for metastatic lung cancer was spent in physical

contact withthe healthcare system. This information may aid shared decision-making for patients who prioritize to maximize time spent at home following a diagnosis of incurable lung cancer.

#61: Stage-standardized and stage-specific survival among men with prostate cancer in the Nordic countries 2004-2016 - the NORDCAN survival studies

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Abstract
Introduction
Prostate cancer survival varies between the Nordic countries, potentially reflecting variation in the distribution of stages at diagnosis. To highlight variation in the diagnostic intensity of prostate cancer, we outlined the differences in stage distributions at diagnosis across the Nordic countries. Specifically, we evaluated whether the variation in cancer survival could be attributed to differences in stage at diagnosis.

Material and methods
In this population-based cohort study, we identified 243,893 men diagnosed with prostate cancer from 2004 to 2016 in Denmark, Iceland, Norway, and Sweden. Country-specific stage distributions at diagnosis were obtained from the NORDCAN survival database. Relative survival and 95% confidence intervals (CI) were estimated using the Pohar-Perme estimator.
Stage-standardized relative survival was estimated by applying pre-weighting based on the stage distribution of the entire Nordic cohort.

Results
The stage distribution of prostate cancer at diagnosis varied between the Nordic countries with the highest proportion of early-stage (0-I) in Sweden and the highest proportion of advanced-stage (IV) in Denmark. After adjusting for differences in stage distribution (i.e., stage-standardization), the 5-year relative survival improved in Denmark and Norway, increasing from 83.9% (95%

CI, 83.2-84.6%) and 91.4% (95% CI, 90.8-92.0%) to 87.3 (95% CI, 86.5-88.2%) and 93.4% (95% CI, 92.8-94.1%), respectively. Conversely, the adjusted 5-year relative survival declined in Sweden from 90.6% (95% CI, 90.3-91.0%) to 88.5% (95% CI, 88.0-89.1%).

Conclusions
The observed variations in prostate cancer survival between the Nordic countries can be largely attributed to differences in stage distribution at diagnosis. This leaves only minor potential for other factors, e.g., therapeutic approaches, to explain the disparities.

#62: DBCG IMN2: Internal mammary node irradiation in 4,541 node-positive breast cancer patients treated 2007-2014

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Abstract
Introduction
Internal mammary node irradiation (IMNI) improves overall survival (OS) in node-positive breast cancer (BC) patients. However, international controversy exists whether the effect remains in the landscape of modern adjuvant therapies. Therefore, the Danish Breast Cancer Group (DBCG) IMN2 study aimed to investigate the effect of IMNI in the era of modern adjuvant therapies.

Material and methods
A nationwide prospective cohort study in node-positive BC patients treated with loco-regional radiotherapy (RT). Exclusion criteria were prior malignancies, bilateral BC, primary systemic therapy, recurrence before RT, and non-standard RT.
IMNI was indicated in right-sided patients but not in left-sided patients. IMNI was 3D-based RT. Systemic adjuvant treatment was taxan-based chemotherapy, tamoxifen/letrozole for endocrine therapy, and trastuzumab for HER2-positive patients. Data were collected from the DBCG database and the Danish Pathology Data Bank. Missing values and inconsistencies were handled with chart reviews. The primary end-point was OS. Secondary endpoints were BC mortality and distant recurrence. Cox regression analyses were used for adjusted hazard ratios (HR).

Results
Between January 2007 and May 2014, a total of 4,541 patients were included. Patient characteristics were distributed evenly between right- and left-sided patients.
Median follow-up was 13.7 years for OS. Survival rates at 15 years were 65.0% in patients with IMNI and 60.8% without leading to an adjusted HR of 0.85 (95%CI, 0.76-0.94; p=0.002). Corresponding HRs were 0.84 (95%CI, 0.74-0.95; p=0.008) for BC mortality and HR 0.87 (95%CI, 0.78-0.98; p=0.025) for distant recurrence. The 15-year cumulative incidence of death from ischemic or valvular heart disease was 0.2% in right-sided patients and 0.7% in left-sided.

Conclusions
IMNI reduced distant recurrences and BC mortality leading to an improved overall survival in node-positive BC patients treated with modern adjuvant therapies.

#63: Statin use and Early Breast Cancer Survival: A Danish population-based cohort study using an emulated target trial approach

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Abstract

Background
Compelling evidence for the role of cholesterol in breast cancer metabolism suggests that cholesterol-lowering medications, such as statins, may improve breast cancer (BC) prognosis. We conducted a target trial to emulate a randomized trial of statin initiation in adjuvant BC patients using observational data.

Methods
We identified 110,160 female patients diagnosed with stage I, II, or III BC and registered in the clinical registry of the Danish Breast Cancer Group between 2000 and 2020. Women with prior invasive breast carcinoma or cholesterol-lowering therapy at diagnosis were excluded. To emulate a target trial of statin initiation after BC diagnosis, each eligible patient was duplicated into a cloned cohort and assigned to one of the two treatment strategies: initiate statins within 36 months of diagnosis or not to initiate statins. Patients were followed from date of diagnosis until deviation of the assigned strategy, emigration, death, or 1 October 2022. The primary endpoint was BC mortality. We used inverse-probability of censoring-weighting (IPCW) to estimate weights based on prognostic factors. We computed hazard ratios (HR) with 95% confidence intervals (CIs) of BC mortality in statin users vs. non-statin users. In secondary analyses, we used multivariable Cox regression models and conducted landmark analysis after 10 years of follow-up to estimate HR of BC mortality and 95% CIs.

Results
From the cloned cohort of 220,320 patients, we enrolled 133,904 BC patients, among whom 9,702 were statin users. The analysis using IPCW yielded a HR of 0.96 (95% CI: 0.91-1.01) for BC mortality in statin users vs. non-statin users. This finding was complemented by the results of the Cox regression (HR 0.81, 95% CI: 0.73-0.90) and the 10-year landmark analysis (HR 0.86, 95% CI: 0.76-0.98), both showing reduced BC mortality among statin users.

Conclusion
The results suggest a potential benefit of adding statins to standard adjuvant BC treatment.

#64: Danish Melanoma Cancer Pathway enables the best patient triage in the world: A Comprehensive Nationwide Study on Skin Cancer and Melanoma Biopsies

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Abstract
Introduction
Due to a multitude of factors, skin cancer incidence is increasing and challenges medical professionals in biopsy decision-making. While skin cancer may have a profound impact on the patient and be costly for society. Internationally, between 2 and 30 benign skin lesions are biopsied for each case of melanoma. Little is known of the cost of this unnecessary collateral damage.

This study evaluates the number and costs of skin biopsies in Denmark over 15 years. It aims to understand the consequence of "kræftpakke filter-funktion" for Benign to Malignant Ratio (BMR) and Number Needed to Biopsy (NNB) and estimate the direct cost of benign skin lesion biopsies due to a suspicion of malignancy and melanoma referred using the Cancer Pathway from the perspective of a public healthcare system.

Methods
The study included 4,033,249 biopsy specimens from 2007 to June 2022 from the Danish Pathology Data Bank, of which 151,988 from the Cancer Pathway were included in the primary analysis of BMR. The national reimbursement rates for biopsies were used, alongside histopathological examination costs extracted from several pathology departments, for a Monte-Carlo simulation of a simple cost and sensitivity analysis.

Results
Overall, the analyses revealed a BMR of 1.6:1 for malignancy, a 2.8 benign melanoma mimics biopsied for every case of melanoma (NNB), and that there had been a 39% increase in skin biopsies from 2007 to 2021. The cost of benign skin biopsies performed using the Cancer Pathway 2021 was DKK 45M, predominantly from the tertiary sector, where most Cancer Pathway biopsies were performed.

Conclusion
This comprehensive nationwide study shows that a healthcare system that employs filtering functions before the biopsy of skin lesions can achieve some of the lowest BMR and NNB reported in the world, but

with the vast majority of benign skin lesions excisions due to suspicion of malignancy being performed in the tertiary sector, which is the most expensive.

#65: A national prospective study of 897 patients and their satisfaction after kilovoltage therapy of basal cell carcinoma

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Abstract
Background
Kilovoltage therapy is a valid treatment option for basal cell carcinomas (BCC), resulting in tumor control rates and cosmetic outcome comparable to surgery. Although BCCs are the most diagnosed neoplasm in humans, the evidence for kilovoltage therapy is mostly based on retrospective reports with heterogeneity in treatment- and patient-related factors. This study aims to report on patient reported satisfaction as well as professional evaluation regarding the cosmetic outcome six months after ended treatment.

Patients and methods
From 1st of January 2020 to 31st of December 2022 a nationwide prospective collection of patient- and treatment data was conducted for patients with BCC in the facial region consecutively referred for kilovoltage therapy during the given time period in five of six Danish centers. Kilovoltage therapy, predominantly 70-100 kV, was delivered as either 40.5-45 Gy over 9-10 fx or 51Gy over 17fx with margins ranging from 5-10 mm. Patients were offered a follow-up consultation six months after ended treatment, where patient reported satisfaction as well as over-all professional evalution based on LENTSOMA-criteria was reported on.

Results
A total of 1133 patients were registered, amongst these 738 (65%) had follow-up data and were included in this study. 711 (96%) of the patients were either satisfied or very satisfied with the cosmetic outcome, which is correlated (p>0.001) with the professional evaluation, in which 97% of cases had no- or minor skin changes. In univariate analysis, the following factors did not have an impact on patient reported satisfaction with cosmesis: age (p=0.5), sex (p=0.4), smoking (p=0.5), fi eld size (p=0.4) and fraction size(schedule (3Gy/fx vs 4.5 Gy/fx) (p=0.3). This is, once again, in accordance with over-all professional evaluation.

Conclusion
Altogether, 96% of patients were satisfied with the cosmetic result after hypofractionated kilovoltage therapy for BCC.

#66: Risk factors for locally advanced non-melanoma skin cancer

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Abstract
Introduction
Non-melanoma skin cancer is considered a “non-aggressive cancer”. It rarely metastasize and the patients very rarely dies from it. It is usually slow growing, but in case of delay in diagnosis and treatment, the lesions can infiltrate the local tissue and cause severe damage. Extensive surgery may then be necessary to manage the disease. For people with low socio-economic status, comorbidities, care dependency and a considerable distance to hospitals with specialized treatment, the risk of delay may increase.

Materials and methods
This is a nationwide, register-based cohort study. All patients with a first-time incidence of basal cell carcinoma (BCC) or squamous cell carcinoma (SCC) over the age of 18 from 2007-2021 are included. We divided the patients into two groups: non-advanced (T-stage of T1, size under 20 mm) and locally advanced (T-stage of ≥T2, size over 20 mm) disease. Data on demographic, socio-economic, health-related, and geographical factors are collected from several national registers. We then analyzed the associations between risk factors and locally advanced disease at time of diagnosis through multivariate logistic regression.

Results
We found 191,032 patients with BCC and 50,680 patients with SCC in the 15-year period. Male sex, older age, shorter education, lower income, living alone, care dependency and a higher degree of comorbidity was associated with increased odds for being diagnosed with a T-stage of T2 or more BCC or SCC. In addition, residence outside the Capital Region was related to advanced cancer stage at diagnosis.

Conclusions
Socioeconomic challenges and region of residence are significantly associated with a higher risk for locally advanced disease at time of diagnosis in BCC and SCC. Targeted initiatives aimed at improving early detection should prioritize vulnerable individuals. Additionally, future research could explore regional differences in diagnostic delays.

#67: Ten years axillary recurrence and survival after omission of axillary lymph node dissection in breast cancer patients with micrometastases or isolated tumor cells in the sentinel node: A Danish national register study

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Abstract
Introduction
In 2012, changes in the national Danish guidelines resulted in omission of axillary lymph node dissection (ALND) in breast cancer patients with micrometastases (pN1mi) or isolated tumor cells (pN0(i)) in the sentinel node (SN). This change has annually spared approximately 450 Danish breast cancer patients an ALND. ALND is associated with lymphedema, paresthesia, functional impairment, and pain. We aimed to investigate the safety of omitting ALND for patients with pN1mi and pN0(i) in the SN with ten years of follow-up.

Materials and methods
This national register-based study included all women with primary breast cancer surgery between 01.01.2008 and 31.12.2021 who had pN1mi and pN0(i) in the SN. Data was retrieved from the Danish Breast Cancer Group (DBCG) database. The primary outcome was axillary recurrence (AR); the secondary outcome was overall survival (OS). OS was estimated using the Kaplan-Meier method and compared with a log-rank test.

Results
5075 patients were included. 62.4% had pN1mi and 37.6% had pN0(i). Analyzing patients with pN1mi or pN0(i) with or without ALND, 0.2% and 1.5% had an AR. OS after ten years of follow-up for patients with pN1mi or pN0(i) was 81.5%; 83.7% for patients with and 79.12% for patients without ALND. (p< 0,01). This difference was statistically significant. When adjusting for risk factors, there was no significant difference in OS between the patients with pN1mi or pN0(i) with and without ALND (p=0.6).

Conclusion
In this extensive register-based study, we found a slightly higher rate of AR after ten years of follow-up in breast cancer patients with pN1mi or pN0(i) in the SN when ALND was omitted. However, the AR rate was low (< 2%), and after adjusting for risk factors, the increased recurrence rate did not affact OS. These results confirm the safety of omitting ALND in these patients.

8. Clinical epidemiology & database research II #68-76

#68: Temporal Trends and Regional Variability in BRAF and KRAS Genetic Testing in Denmark (2010-2022): Implications for Precision Medicine

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Abstract
Introduction
This study aims to evaluate the developments in the testing of Kirsten Rat Sarcoma viral oncogene homolog (KRAS) and v-Raf murine sarcoma viral oncogene homolog B1 (BRAF) mutations across diff erent cancer types and regions in Denmark from 2010 to 2022.

Materials and Methods
Using comprehensive data from the Danish health registries, we linked molecular test results from the Danish Pathology Registry with cancer diagnoses from the Danish National Patient Registry between 2010 and 2022. We assessed the frequency and distribution of KRAS and BRAF mutations across all cancer types, years of testing, and the fi ve Danish regions.

Result
The study included records of KRAS testing for 30,671 patients and BRAF testing for 30,860 patients. Most KRAS testing was performed in colorectal (78%) and lung cancer (18%), and BRAF testing in malignant melanoma (13%), colorectal cancer (67%), and lung cancer (12%). Testing rates and documentation mutational subtypes increased over time. Reporting of wildtype results varied between lung and colorectal cancer, with underreporting in lung cancer. Regional variations in testing and reporting were observed.

Conclusions
Our study highlights substantial progress in KRAS and BRAF testing in Denmark from 2010 to 2022, evidenced by increased and more specifi c reporting of mutational test results, thereby improving the precision of cancer diagnosis and treatment. However, persistent regional variations and limited testing for cancer types beyond melanoma, colorectal, and lung cancer highlight the necessity for a nationwide assesment of the optimal testing approach.

#69: The association between deficient mismatch repair subtypes and oncological outcomes in localized colorectal cancer – A nationwide cohort study

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Abstract
Introduction
Proficient and deficient mismatch repair (MMR) status have been shown to impact prognosis and response to both chemotherapy and immunotherapy. However, it is unknown if the loss of certain MMR proteins is of importance. This study investigated the association between different deficient MMR (dMMR) expression patterns and oncological outcomes in patients with localized colorectal cancer.

Materials and methods
In this Danish cohort study, we included patients who underwent surgery with curative intent for localized dMMR colorectal cancer between 2009 and 2020. In the Danish Colorectal Cancer Group database, a total of 36,765 patients with colorectal cancer were identified, and patient-level data were extracted. Then, patients with proficient MMR status, metastatic disease, who underwent emergency surgery, or who received neoadjuvant treatment were excluded. Finally, propensity-score matching in a 1:1 ratio was applied. The study aimed to investigate the association between loss of MSH2/MSH6 versus loss of MLH1/PMS2 expression and overall survival (OS) and disease-free survival (DFS).

Results
After the exclusion process, 3,625 patients with localized dMMR colorectal cancer were eligible for inclusion. The median age of the cohort was 75 years with a median follow-up of 4.3 years. Before matching, the MSH2/MSH6 versus MLH1/PMS2 groups showed a significant association with OS in the analysis (hazard ratio 0.49; 95% CI, 0.36-0.64) and DFS (hazard ratio 0.72; 95% CI, 0.54-0.95). After matching, 556 patients were included in the analysis, which showed a statistically signifi cant association between a loss of MSH2/MSH6 versus MLH1/PMS2 expression and OS (hazard ratio 0.60; 95% CI, 0.37-0.94), but not DFS (hazard ratio 0.84; 95% CI, 0.54-1.30).

Conclusions
A significant association was found between loss of MSH2/MSH6 versus loss of MLH1/PMS2 expression and OS in patients with localized dMMR colorectal cancer.

#70: The Association Between Having Adult Children and Survival After Colon and Rectal Cancer Among Older Adults: A Danish Register-Based Cohort Study

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Abstract
Introduction
Prior research links social support to survival in colorectal cancer patients, but the specific impact of having adult children remains unexplored. This study aims to investigate this association.

Materials and methods
The study included individuals over 60 years diagnosed with colorectal cancer between 2001 and 2021 born after 1935 (N=39,495). Two Cox regression models were performed with adjustment of birth cohort, age at diagnosis, sex, education, residence, and cohabitation status. Firstly, the 1-year survival was estimated, secondly, the conditional 5-year survival was estimated among patients alive one year post-diagnosis. The association between the number of children and the sex of the adult children and survival was examined among those with adult children (N=34,404).

Results
Within the first year of follow-up, not having adult children was associated with a 1.34 [95% CI 1.22;1.47] and 1.35 [95% CI 1.18;1.54] times higher hazard of death for colon and rectal cancer patients, respectively, compared to having adult children. Among patients alive one year post-diagnosis, the corresponding estimates for five years of follow-up were 1.08 [95% CI 0.99;1.18] and 1.26 [95% CI 1.13;1.40]. For colon cancer patients, having one child was associated with a higher hazard of death compared to having two children (1-year survival: 1.15 [95% CI 1.05;1.26] & conditional 5-year survival: 1.08 [95% CI 1.00;1.17]). Having three or more children was neither associated with a higher nor lower hazard of death. There was no association between the sex of the children and death.

Conclusion
Older colorectal cancer patients without adult children had a higher hazard of death compared to those with adult children, particularly in the first year post-diagnosis. The study provides new insights into social networks in colorectal cancer survival.

#71: Mechanisms of Missingness and Generalizability of Patient Reported Outcome Measures in Colorectal Cancer Survivors – Assessing The Reasonableness Of The “Missing Completely At Random” Assumption

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Abstract

Background

Patient-Reported Outcome Measures (PROM) provide important information, however, missing PROM data threaten the interpretability and generalizability of findings by introducing potential bias. This study aims to provide insight into mechanisms of missingness and inform future researchers on generalizability and possible methodological solutions to overcome missing PROM data problems during data collection and statistical analyses.

Methods

We identified 10,236 colorectal cancer survivors (CRCs) above 18y, diagnosed between 2014 and 2018 through the Danish Clinical Registries. We invited a random 20% (2,097) to participate in a national survey in May 2023. We distributed reminder e-mails at day 10 and day 20, and compared Initial Responders (response day 0-9), Subsequent Responders (response day 10-28) and Non-responders (no response after 28 days) in demographic and cancer-related characteristics and PROM-scores using linear regression.

Results

Of the 2,097 CRCs, 1,188 responded (57%). Of these, 142 (7%) were excluded leaving 1,955 eligible CRCs. 628 (32%) were categorized as initial responders, 418 (21%) as subsequent responders, and 909 (47%) as non-responders. Differences in demographic and cancer-related characteristics between the three groups were minor and PROM-scores only marginally differed between initial and subsequent responders.

Conclusion

In this study of long-term colorectal cancer survivors, we showed that initial responders, subsequent responders, and non-responders exhibit comparable demographic and cancer-related characteristics. Among respondents, Patient-Reported Outcome Measures were also similar, indicating generalizability. Assuming Patient-Reported Outcome Measures of subsequent responders represent answers by the non-responders (would they be available), it may be reasonable to judge the mechanisms of missingness as Missing Completely At Random.

#72: Performance of Natural Language Processing for Information Extraction from Electronic Health Records within Cancer: A Systematic Review

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Abstract
Introduction
Natural language processing (NLP) has emerged as a valuable solution for information extraction (IE) in clinical textual data. In recent years, the use of NLP in cancer research has gained considerable attention, with numerous studies exploring the effectiveness of various NLP techniques for identifying and extracting cancer-related entities from medical texts. We aim to summarize the performance differences of various NLP models for IE within the context of cancer to give an overview of the relative performance of existing models.

Material and methods
We have searched five databases (PubMed, Scopus, Web of Science, ScienceDirect, and MEDLINE) for articles extracting cancer related entities from clinical text. To compare the performance of IE, only articles comparing at least two models on the same dataset were included, leading to 14 articles being eligible for inclusion. We extracted the NLP models and performances based on F1 scores. Each of the models has been categorized into the following categories: Rule-based, CRF-based, Bidirectional transformer, Neural Network, Ensemble, and Support Vector Machine. For each article, we calculated the performance difference of each of the implemented categorizations.

Results
The performance of the best category for each article ranged from 0.73 to 0.935. Ensemble outperforms every other category followed by bidirectional transformer only being outperformed by ensemble with 0.014. Neural network outperforms CRF-based and Rule-based. CRF-based outperforms rule-based.

Conclusion
NLP has demonstrated its ability to identify and extract cancer-related entities from unstructured data. Generally, all models show excellent performance in terms of F1 score, and the more advanced models outperform the less advanced models. However, ensemble models are the best performing followed by bidirectional transformers. Rule-based applications for IE are still competitive in terms of performance in this specific context.

#73: Leveraging England's comprehensive cancer database through synthetic data — demonstrated using a case of clinical trial participation

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Abstract
Introduction
Data and privacy protection laws have become increasingly restrictive regarding access to sensitive information, which is essential for healthcare research. Furthermore, privacy protection becomes more complex when conducting cross-national healthcare studies. Synthetic data have emerged as a promising solution for working with sensitive information. In this study, the synthetic cancer dataset “Simulacrum” from the English National Health Services (NHS) is used as a case to evaluate the viability of synthetic data as an option for scientists in healthcare research.

Materials and methods
An analysis of clinical trial participation was made using Danish data to be replicated in Simulacrum. The Simulacrum v. 2.10 dataset was imported into an Oracle database, and SQL queries were tested and implemented using an ODBC connection in R. The data was analyzed, returning results as tables. After initial testing on Simulacrum, the analysis was sent to NHS Digital for execution on real data. We await the results from the model on the real cancer cohort patients from NHS’s database.

Results
We found that Simulacrum was excellent for replicating the analysis and completing a workflow using SQL and R that could be executed on the real dataset. The advantage of using Simulacrum was the availability of data structures, completeness, and dimensions. However, we found that the results from Simulacrum had no analytic value.

Conclusions
We found the Simulacrum dataset to be a valuable resource for working with sensitive health data, as it created the opportunity to 1) understand the structure and naming of the real data, 2) build and test an analysis, 3) easy access to execute an analysis on the real data without privacy concern 4) sharing of workflow with collaborators among collaborators.

#74: Sex Differences in Cancer Incidence and Survival — A Nationwide Danish Registry Study

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Abstract
Introduction
Despite indications of sex differences in cancer incidence and survival, few comprehensive studies based on robust data sources have been conducted. Moreover, the underlying reasons for sex differences in cancer remain largely unknown. This highlights the importance of examining differences in incidence and survival between sexes based on high-quality Danish registries and identifying underlying factors behind sex differences in cancer.

Material and methods
We identified all incident cases of cancer in the period 2004-2020 in the Danish Cancer Registry. Differences in incidence and survival were assessed for 35 cancers occurring in both males and females. We estimated incidence rate ratios (IRRs) and excess mortality ratios (EMRs) using Poisson regression models adjusted for age and year of diagnosis. Using data from Statistics Denmark, we examined IRRs and EMRs according to cohabitation status. Effect modification of sex on death by cohabitation status, education level, and comorbidity were further assessed.

Results
The study population comprised 197,904 males and 149,819 females. IRRs were statistically significantly higher in males in 24 of 35 cancers, and EMRs were statistically significantly higher in 15 of 35 cancers. Females had increased incidence in 4 of 35 cancers and poorer survival in 2 of 35 cancers. IRRs and EMRs were particularly elevated in males living alone. Generally, the effect of sex on death tented to be modified by cohabitation status for most cancers; thus, living alone had a greater impact on survival in males than in females. Education and comorbidity modified the effect of sex on death in a few cancers.

Conclusion
Across most cancers, males had higher incidence and mortality than females. Incidence and mortality were especially increased in males living alone. These findings underscore the need for studies aimed at identifying modifiable factors that drive sex differences in cancer and for addressing sex disparities.

#75: Timing of recurrence following cytoreductive surgery and hyperthermic intraperitoneal chemotherapy for peritoneal metastases of colorectal origin: risk factors and prognosis

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Abstract
Introduction
Cytoreductive surgery (CRS) with hyperthermic intraperitoneal chemotherapy (HIPEC) has signifi cantly improved the 5-year survival for colorectal cancer (CRC) patients with peritoneal metastases (PM). However, recurrence remains a signifi cant challenge. Identifying risk factors of early recurrence (ER) supports optimal decision-making and follow-up. Our study aimed to characterize patients with early and late recurrence, to identify risk factors of ER, and assess the impact of ER on overall survival (OS).

Materials and method
From June 2006 to December 2020, a prospective cohort study included 310 patients with CRC and PM who underwent CRS+HIPEC at a single national center. Recurrence diagnosed ≤ 6 months after CRS+HIPEC was defi ned as early; >6 months as late. Multivariate Cox regression identified ER risk factors. Kaplan-Meier analysis was made to estimate OS.

Results
Of 310 patients, 247 patients (79.7%) experienced recurrence: 65 (26.3%) had ER, 182 (73.7%) had late recurrence. Median follow-up was 10.3 months. Characteristics of patients with early and late recurrence will be described (currently not completed). Signifi cant risk factors of ER were PCI score (per point increase) (HR 1.10, 95% CI: 1.05; 1.16) and the presence of extraperitoneal metastases prior to CRS+HIPEC (HR 2.03, 95% CI: 1.12; 3.68). Completed postoperative chemotherapy reduced the risk of ER (HR 0.41, 95% CI: 0.22; 0.79). Patients with ER had a signifi cantly decreased median OS of 16.8 months (12.1; 22.0) compared to 24.3 months (21.4; 28.3) for those with late recurrence (p=0.03).

Conclusion
PCI score and extraperitoneal metastases increases the risk of ER, while postoperative chemotherapy lowers the risk. Patients with ER after CRS+HIPEC for CRC PM have a decreased OS. Consideration of risk factors is crucial in CRC PM management. The role of postoperative chemotherapy in reducing the risk of ER following CRS+HIPEC underscores its importance in adjuvant treatment protocols.

#76: Quality Indicators and development targets in the Danish Clinical Quality Registries in cancer and cancer screening

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Abstract
Introduction
The Danish clinical quality registries contribute to monitoring and improving the quality of clinical care, using clinical quality indicators and defi ned development targets, mostly referred to as “standards”. This study aims to investigate the fulfillment of clinical quality indicator standards in the Danish clinical quality registries in cancer and cancer screening to assess the ambition level for the defi ned standards.

Materials and methods
This study included data from annual reports in the 27 Danish clinical quality registries in cancer and cancer screening. The most recent reports were downloaded on the 13th of December 2023. Indicators were included if they: evaluated a 12-month period, presented in an indicator table including a well-defi ned standard with a desired direction, and presented the proportion of patients and number for which the standard could be and was fulfilled. Data was extracted on national and regional levels for the last three reported years, and fulfillment of standards was presented as the proportion of indicators which fulfilled the standard within each unit of comparison.

Results
A total of 216 quality indicators were included. On the national level, 75% of the clinical indicator standards were fulfilled, and on the regional level 67%. Fulfillment within the registries varied from 5 to 100% on national and 12 to 99% on regional level. Result indicators were more often fulfilled than process indicators.

Conclusions
The approach to defining clinical quality indicator standards as conservative or ambitious development targets varied in the 27 Danish clinical quality registers in cancer and cancer screening. Few registries have defi ned very ambitious or conservative standards, but most of the registries have defi ned standards for the quality indicators at a level where the standard is met in some regions, hereby possibly promoting regional data-driven quality improvement in clinical care.

9. Screening & early diagnostics #77-86

#77: "We're the very bottom, so it's going to be hard for you to 'catch any fish' around here..." Understanding vulnerable Greenlanders' perspectives on cancer and barriers to screening in Denmark – A qualitative study

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Abstract

Introduction
Cancer is a major global health concern. Unfortunately, Indigenous populations such as Greenlanders living in Denmark, face significant disparities in cancer risk, incidence, diagnosis and care quality. In Denmark, vulnerable Greenlanders face challenges accessing cancer screening. The aim of this study was to explore their perceptions of cancer, barriers to participation in cancer screening, and potential for developing a tailored intervention.

Materials and methods
This qualitative study was based on participant observations and qualitative interviews. The sample comprised 46 participants from four distinct drop-in centres. Of these, 28 were vulnerable Greenlanders (19 women and 9 men), 9 were staff members (6 women and
3 men), and 6 were relatives (4 women and 2 men). The data were analysed through inductive content analysis.

Results
The vulnerable Greenlanders in our study faced challenges such as substance abuse, cognitive issues, and loneliness, impacting their views on cancer and screening. Despite initial avoidance of cancer discussions and personal risk, there was a general understanding of early detection benefits. One leading obstacle hindering participation in cancer screening was their life circumstances, particularly the challenge of managing health without external support. Yet, most expressed a willingness to engage, highlighting the importance of regular, empathetic face-to-face awareness initiatives to boost motivation.

Conclusions
For vulnerable Greenlanders in Denmark participation in cancer screening programmes was positively viewed for most but could bechallenging. Different intervention ideas raised by the vulnerable Greenlanders, relatives and staff members could guide the development of strategies to increase participation rates.

#78: Risikofaktorer og overlevelse ved uplanlagte diagnostiske forløb for myelomatose

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Abstract
Introduktion
Myelomatose debuterer ofte med uspecifikke symptomer, og mange patienter diagnosticeres i uplanlagte forløb (fx under akut indlæggelse). Vi undersøgte sammenhængen mellem at få myelomatosediagnosen i uplanlagte forløb og patient- og sygdomskarakteristika samt overlevelsen.

Materiale og metode
Alle patienter diagnosticeret med myelomatose i Danmark i 2014-2018 blev inkluderet i et nationalt registerbaseret studie. Patienter blev kategoriseret som diagnosticeret i et uplanlagt forløb, hvis de var registreret med en ikke-planlagt indlæggelse inden for 30 dage før diagnosen, og ingen anden diagnosevej var registreret før dette. Uplanlagte forløb blev sammenlignet med alle andre diagnoseveje samlet ved hjælp af regressionsanalyser og Kaplan-Meier kurver.

Resultater
Vi inkluderede 1.997 patienter med myelomatose, hvor 30 % var diagnosticeret i uplanlagte forløb. Diagnose i et uplanlagt forløb var forbundet med høj komorbiditet, ingen tidligere kræftdiagnose, få kontakter i almen praksis 18-36 måneder før diagnosen, højt kræftstadie, højrisiko cytogenetik og komplikationer ved diagnosen. Fx 40,3 % (95 % CI: 35,7-44,8) for patienter med færrest kontakter i almen praksis og 24,9 % (95 % CI: 20,9-29,0) for patienter med flest kontakter, og 65,2 % (95 % CI: 51,6-78,9) og 29,0 % (95 % CI: 27,0-31,1) for patienter hhv. med og uden behov for dialyse på diagnosetidspunktet. Patienter diagnosticeret i et uplanlagt forløb havde kortere overlevelse (hazard ratio 1,54 (95% CI: 1,30-1,81)).

Konklusioner
Diagnose i uplanlagt forløb var associeret med få kontakter i almen praksis, høj komorbiditet, højt kræftstadie, højrisiko cytogenetik og komplikationer. Yderligere havde patienter diagnosticeret i uplanlagte forløb dårligere overlevelse end patienter diagnosticeret i elektive forløb. Tidlig diagnostik og forebyggelse af uplanlagte diagnostiske forløb kan være vigtigt for at forbedre overlevelsen ved myelomatose.

#79: Brug af sundhedsydelser og veje til diagnosen før hæmatologisk kræft

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Abstract

Introduktion
Hæmatologisk kræft debuterer ofte med uspecifikke symptomer, hvilket kan forsinke diagnosen. Dette studie undersøger brug af sundhedsydelser i almen praksis og på hospitalet forud for en hæmatologisk kræftdiagnose mhp. muligheder for tidligere diagnostik.

Materialer og metoder
Studiet blev udført som et nationalt kohortestudie og inkluderede patienter diagnosticeret med myelomatose, lymfom, akut og kronisk leukæmi i perioden 2014-2018. Hver patient matchedes med 10 referencer. Diagnoseveje blev inddelt i uplanlagte (en akut hospitalsindlæggelse 30 dage op til diagnosen) og elektive forløb (fx kræftpakke). Brug af sundhedsydelser blev angivet med månedlige rater og incidens rate ratioer (IRR).

Resultater
I alt blev 11,870 patienter med hæmatologisk kræft og 118,710 referencer inkluderet. Kvindelige patienter med et uplanlagt forløb havde øget kontakt til almen praksis i forhold til referencerne fra 19 måneder før diagnosen; IRR steg fra 1.13 (95% CI 1.05-1.23) til 2.25 (95% CI 2.1-2.40) en måned før diagnosen. Derudover fik kvindelige patienter lavet flere tests i almen praksis fra 16 måneder før diagnosen, og havde flere kontakter og radiologiske undersøgelser på hospitalet fra hhv. 24 og 17 måneder før diagnose. Lignende mønstre blev fundet for mandlige patienter. Der var ikke forskel på hyppighed af kontakter i sundhedsvæsnet for patienter med uplanlagte og elektive diagnoseveje. Dog havde kvinder i uplanlagte forløb flere hospitalskontakter end kvinder i elektive forløb.

Konklusioner
Øget brug af sundhedsydelser i almen praksis og på hospitalet fra op til to år før en hæmatologisk kræftdiagnose indikerer et potentiale for tidligere diagnostik. Der var dog variation i brug af sundhedsydelser på tværs af køn, hæmatologisk kræfttype. Overordnet set var patientens diagnosevej ikke associeret til brug af sundhedsydelser.

#80: Brug af CT-scanning og røntgenbilleder af danske patienter med lungekræft før diagnosen fra 2010 til 2023

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Abstract

Formål

Formålet med denne undersøgelse er at kvantificere den respektive brug af røntgen og CT-scanninger under diagnostisk udredning af danske patienter med lungekræft. Danmark har en af verdens højeste forekomster af lungekræft og det højeste antal personer, der dør af lungekræft per indbygger. Lungekræftvejledningen fastslår, at den standard radiologiske modalitet er en CT-scanning (følsomhed > 95%), hvis der er mistanke om lungekræft. Imidlertid bliver kun ca. 25% af patienterne, der senere får diagnosen lungekræft, der direkte bliver henvist til et lungekræftpakkeforløb på grund af alarm-symptomer. Ved henvisning til en lungekræftpakke er CT-scanning obligatorisk. For de resterende patienter, der ikke direkte henvises, men stadig viser sig at have lungekræft, har røntgen (følsomhed < 75%) været den faktiske initiale radiologiske modalitet, hvilket kan medføre forsinkelse på grund af falsk negative tests og muligvis være en årsag til diagnose i sent stadie.

Metode

Vi gennemførte en retrospektiv kohorteundersøgelse af alle patienter, der fik diagnosen lungekræft i Danmark fra 2010 til 2023 ved hjælp af landspatientregistret for at fastslå, hvilken modalitet af radiologi (røntgen og/eller CT) der var blevet brugt 12, 6, 3 og måneder før diagnosetidspunktet.

Resultater

I 2020 fik knap halvdelen af de danske patienter, der fik lungekræft, en røntgenundersøgelse af thorax som den første testmodalitet inden for et år før diagnosen.
Yderligere dataanalyse er i øjeblikket i gang med fokus på patientkarakteristika (stadie og mortalitet) i relation til behandlingsmodaliteterne. Resultaterne vil blive præsenteret på konferencen.

Konklusioner

Røntgenundersøgelser af thorax bruges stadig - trods lav sensitivitet - hyppigt, hvor lungekræft senere diagnosticeres, og det kan være et kvalitetsproblem, som bør rettes i bestræbelser for at opnå tidlig diagnostik i lavt stadie.

#81: Changes in healthcare-seeking and diagnostic evaluation of patients with lung cancer symptoms over a decade – a population-based study

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Abstract
Introduction
Healthcare-seeking when noticing symptoms and subsequent diagnostic evaluation is a prerequisite for timely diagnoses of lung cancer. Several factors may have altered the perception of lung cancer symptoms and hence contacts to the general practitioners (GPs) over the last decade. Further, focus on timely diagnosis and changes in the fast-track lung cancer diagnostic pathway may have influenced referral for clinical evaluation.

Objective
Based on two surveys linked to register data this study 1)compare the proportions of GP contacts and subsequent clinical evaluation among individuals reporting lung cancer symptoms in 2012 and 2022, and 2) analyse factors associated with GP contacts and clinical evaluation.
Materials and methods:
Survey among two random samples of 100,000 individuals ≥20 years old in 2012 and 2022. Survey data included lung cancer symptoms (prolonged coughing/hoarseness, hemoptysis, dyspnea), GP contacts and smoking status. Register data on clinical evaluation (X-ray and/or CT/PET-CT scan).

Results
In total 49,706 and 31,415 individuals responded in 2012 and 2022, respectively. Overall, the proportion of GP contacts were higher in 2022 (45.3%) than in 2012 (39.6%), mainly due to more contacts with dyspnea (49.7% vs. 60%). Opposite the proportion of GP contacts with hemoptysis decreased from 48% to 42%. Men (OR 0.78, 95% CI: 0.69-0.87) and individuals currently smoking (OR 0.72, 95% CI: 0.61-0.85) unaltered to be less likely to seek care.

Conclusion
Healthcare-seeking with lung cancer symptoms was higher in 2022, except regarding hemoptysis. Individuals who smoked and men still had lower healthcare-seeking. This emphasizes a need of efforts targeting vulnerable groups at risk of omitting care seeking in both primary- and secondary care settings to improve timely diagnosis including adherence to the diagnostic evaluation and treatment. Also, it could be considerable in planning of the upcoming lung cancer screening program.

#82: Cancer symptom experience and healthcare-seeking in the Danish population over the last decade. Knowledge from two cross-sectional studies in 2012 and 2022

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Abstract
Introduction
Healthcare-seeking with symptoms indicative of cancer is a prerequisite for timely diagnosis. Several factors, including patient characteristics, political initiatives and campaigns advocating for cancer awareness and timely diagnosis, may affect symptom experience, and healthcare-seeking behavior. Yet, any development in symptom experiences, and healthcare-seeking over time remains to be investigated. We aim to compare and analyse the frequency of cancer symptoms, and the proportion of contacts to the general practitioner (GP) in 2012 and 2022.

Methods
Two population-based surveys, the Danish Symptom Cohort, from 2012 and 2022, regarding symptom experience, and GP contact. To each survey 100,000 randomly selected adults were invited. In this study we focus on both specific cancer symptoms and non-specific symptoms. Analyses include descriptive statistics on symptom experience and contact to the GP, and multivariable logistic regression models on gender and age's association with healthcare-seeking.

Results
This study includes 49,706 and 31,415 respondents from 2012 and 2022, respectively. Symptom frequency was significantly higher for most symptoms in 2022. Overall, we found a tendency of higher healthcare-seeking among patients with cancer-specific symptoms, except for hoarseness and/or cough. Yet, only 40.6% of patients with bleeding contacted the GP in 2022. We found no unidirectional change for contact to the GP among non-specific symptoms.
Men were less likely to contact the GP with most symptoms in 2022, while high age was associated with GP contact, with odds increasing with higher age categories.

Conclusion
Overall, higher symptom prevalences and higher proportions of healthcare-seeking was observed for cancer-specific symptoms in 2022. The changes were less profound for non-specific symptoms, and more detailed analyses should be conducted to understand the different patterns, and hence enable targeted interventions when warranted.

#83: Colorectal cancer incidence following a negative colonoscopy in FIT-based screening – Results after 8 years of FIT-screening in Denmark

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Abstract
Introduction
Since implementation of the Danish Bowel Screening Program in 2014, participant with a positive faecal immunochemical test (FIT) screening, but a subsequent normal colonoscopy(NC), has been quarantined from the screening program for 8 years. However, the evidence for this quarantine is limited. We estimated the CRC risk after a positive FIT and NC and compared it to a general unscreened population.

Methods
Using nationwide registers, we compared screening participants with a NC to random selected unscreened controls from birth cohorts 9 years younger (ratio 1:28). Controls were assigned a pseudo-colonoscopy date similar to the NCs, just 9 years prior. Outcome measures were cases pr. 10.000 person years and relative risk(RR) of CRC using the pseudo value approach.

Results
We included 29.936 with a NC and 842.096 controls with a median follow-up time of 5.8 and 5.7 years, respectively. At 8 years' follow-up the overall adjusted RR of CRC was 0.75 (0.64;0.86) for the NC-group compared to controls. Women below 60 and women in the 70's did not have a lower risk compared to controls (RR 1.41 (0.99;2.02) and RR 0.97 (0.72;1.30). A reduction was found among men and women in the 60's (0.65 (0.48;0.88) and 0.64 (0.45;0.92)) and men above 70 years (0.63 (0.46;0.87)).

Conclusions
While the overall RR was lower, it might not justify 8 years of quarantine. Women and younger age groups having a NC after a positive FIT might not receive the benefit of screening with current guidelines. Transfer of evidence from non-FIT screening to FIT screening should be done carefully and a more personalized approach to risk stratification are warranted.

#84: Risk and risk factors for lymph node metastasis in women with cervical cancer with a depth of invasion of ≤5 mm and a horizontal spread of >7 mm

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Abstract
Introduction
In the FIGO 2018 classification, women with clinically visible cervical cancer and a depth of invasion ≤5 mm and a horizontal spread of >7 mm, are now classified as stage IA instead of IB. This stage shift may reduce the likelihood of surgical lymph node staging. It is therefore crucial to estimate the risk and risk factors of lymph node metastasis (pN+) in this group.

Materials and methods
Women with cervical cancer between 2005 and 2022 were identified from nationwide population-based registries from the Netherlands, Denmark and Sweden. Inclusion criteria were squamous cell carcinoma or adenocarcinoma, FIGO 2009 stage IB1, a depth of invasion ≤5 mm and horizontal spread of >7–≤40 mm (independent of visibility), treatment with radical hysterectomy or radical trachelectomy, and surgical nodal staging. Logistic regression was used to identify risk factors of pN+.

Results
We included 992 women (pN+ 4.1%; n=41). Lymphovascular space invasion (LVSI) was a significant risk factor of pN+ (odds ratio 4.28, 95% confidence interval 2.24–8.37). Accordingly, the risk of pN+ was at least 7.3% in LVSI-positive tumours. The risk was lowest in LVSI-negative tumours with a size of >7–≤20 mm, although this depended on depth of invasion and histological subtype (pN+ range 0.6–5.1%).

Conclusion
All women with LVSI-positive cervical cancer with a depth of invasion ≤5 mm and a horizontal spread >7 mm, must undergo surgical lymph node staging. In LVSI-negative tumours, tumour size, depth of invasion and histology must be considered when discussing (omitting) nodal staging with the patient.

#85: Frailty in Older Patients with Cancer and the Association with Antineoplastic Treatment and Treatment Adherence: Findings of a Prospective Geriatric 8 Cohort Study (PROGNOSIS-G8)

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Abstract

Introduction
Frailty is common in older patients with cancer and can impact their ability to tolerate oncologic treatment. Therefore, frailty screening, i.e. the Geriatric 8 (G8), is recommended. While the G8 has shown a significant association with survival, the relationship with treatment adherence remains unclear. Our study sought to investigate the association between frailty with the G8 (≤14) and i) receiving standard antineoplastic treatment and ii) antineoplastic treatment adherence within 9-months.

Materials and methods
Patients ≥70 years with solid cancers were screened with the G8 at treatment initiation (June 20 - October 21). Baseline patient characteristics, cancer type, stage, and 1st line antineoplastic treatment were collected via medical records. Treatment was compared to national guidelines, to assess if it was standard. After 9-months, 1st line treatment adherence was registered, noting deviations from the initial treatment plan. Adjusted Logistic regression analysis with Lasso regularization and Hosmer-Lemeshow goodness-of-fit assessment was conducted.

Results
1,398 patients were screened with the G8 (65%, n=908 frail). The mean age of patients was 77 years (SD 5), 55% were men, and 54% received treatment with curative intent (n=704), 39% with palliative intent (n=541) and 11% did not receive treatment. The predominant diagnoses among patients were lung (27%), urogenital (24%) gastrointestinal (19%) and breast cancer (14%). Patients with G8 frailty were less likely to be offered standard treatment (OR 0.49; 95%CI 0.37-0.66). Follow-up data from patients receiving treatment showed that 63% adhered to the initial treatment plan with poorer adherence seen in patients with G8 frailty (0.57 OR 95%CI 0.42-0.77).

Conclusion
Our findings suggest that the G8 might be used to identify a subset of older patients at greater risk of experiencing poor antineoplastic treatment adherence and who may benefit from initial treatment modifications.

#86: hrHPV testing in first-void urine as a novel cervical cancer screening modality: A diagnostic test accuracy study

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Abstract
Introduction
In several countries with well-established cervical cancer screening programs including Denmark, under-screened women account for 50% of cervical cancers. To reach under-screened women, urine collection for high-risk human papillomavirus (hrHPV) testing has therefore gained increasing interest as a non-invasive cervical cancer screening modality. While urinary hrHPV testing has been found effective in reaching under-screened, evidence on its clinical accuracy to detect treatable high-grade cervical intraepithelial neoplasia (CIN2+ and CIN3+) is very sparse and inconsistent. Therefore, this study explored the relative clinical sensitivity of hrHPV testing in first-void urine (FVU) to detect CIN2+ and CIN3+ compared to hrHPV testing on clinician-collected cervical samples.

Materials and methods
In a diagnostic test accuracy study, paired FVU (index test) and cervical samples (comparator test) were obtained from 325 women aged 23-64 years who were either referred for colposcopy and biopsy taking or a cervical excision (reference test). Samples were tested using Allplex HR HPV DNA extended genotyping assay.

Results
Of the 325 women, 145 (44.6%), 180 (55.4%), and 138 (42.5%) were diagnosed with <CIN2, CIN2+, and CIN3+, respectively. The sensitivity to detect CIN2+ (ratio: 0.97, 95% CI: 0.92-1.02, p=0.33) and CIN3+ (ratio: 0.95, 95% CI: 0.90-1.00, p=0.09) using hrHPV testing in FVU samples was not significantly different to hrHPV testing in cervical samples, whereas specificity for <CIN2 (ratio: 0.67, 95% CI: 0.46-0.96) was significantly lower in FVU than on cervical samples.

Conclusions
We proved that hrHPV testing in FVU was non-inferior to testing on clinician-collected cervical samples to detect cervical (pre)-cancer. Accordingly, hrHPV testing in FVU could be considered a clinically safe screening modality to reach under-screened populations and could become an important part in the cervical cancer elimination plans.

10. Personalized medicine, biomarkers & diagnostics I #87-96

#87: The prognostic value of baseline CT-based body composition, functional status, and systemic inflammation in older adults with metastatic gastrointestinal cancers – A pooled analysis of two prospective Nordic cohorts

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Abstract
Introduction
Proper patient selection for palliative systemic treatment is crucial in older adults with metastatic gastrointestinal cancers (mGIC). Information on CT-based body composition, physical function, and systemic infl ammation obtained at the time of diagnosis has the potential to support prognostic understanding and shared decision-making ensuring tailored care in a population where frailty is common.

Methods
We investigated the prognostic value of CT-based body composition (abdominal muscle compartment (AMC) and adipose tissue, intramuscular (IMAT), visceral (VAT), and subcutaneous (SAT)), functional status (ECOG PS), and systemic infl ammation (neutrophil/lymphocyte ratio (NLR), Glasgow Prognostic Score (GPS), and CRP) regarding overall survival (OS) in older adults with mGIC. We included patients in this analysis from two prospective cohorts enrolling adults ≥70 years with mGIC between 2015-2018. CT-scans, ECOG PS, and blood samples were collected at baseline. Descriptive statistics, survival analysis, and Cox regression were applied; moreover, C-statistics were estimated.

Results
337 patients (206 men) were eligible with a median age of 76 years (IQR: 72-79); 70% had colorectal cancer. While body composition parameters were significantly associated with body-mass index, CRP, GPS, and NLR

were correlated with ECOG PS, weight loss, and se-LDH. In multivariable analyses for OS, patients with higher AMC had lower risk for death (HR=0.67, 95% CI: 0.48-0.92, p=0.013); patients presented with impaired functional status (ECOG PS 1-2) or systemic inflammation (CRP>10, GPS>0) had significant higher risk for shorter OS.

Conclusion
Increased muscle mass reduced the risk of early death in older adults with mGIC. ECOG PS and CRP are accessible in clinical practice; this important prognostic information should be included in the shared decision-making process.

#88: In-house 3D printed porous implants: in-vivo study of osseointegration

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Abstract
Introduction
Total tumour removal is the primary factor of consideration in surgical resection. Several techniques exist for tumour reconstructive surgery. Recently, 3D printing has undergone tremendous development and now has important applications in orthopaedic. A major improvement is the possibility to print prosthesis, which are custom made for the single patient. Currently, when a customised 3D printed prosthesis is needed, an outside order must be placed, and the procedure is usually time consuming, making it impossible to fall within the time interval of the law. A collaboration between a 3DP centre in Aarhus University Hospital (AUH) and the Danish Technological Institute (DTI), allow us to manufacture custom-made 3D printed metal implant in-house. Aim of this study was to assess the osseointegration of 3D-printed titanium implants through a validated randomised animal study.

Methods
20 stable, non-weight-loaded, 6*10 mm cylindrical implants were 3D printed by DTI: 10 with a rough and 10 with a smooth surface. Implants were randomised and implanted into the left humerus of 20 skeletally mature sheep. After 4 weeks of observation all sheep were euthanised. The specimens were collected and cut into blokes, each containing an implant and surrounding tissue. Biomechanical testing was performed as failure by push-out test on an Instron Universal Test Machine.

Results
Implants with a smooth surface demonstrate complete absence of osseointegration, as they fall out of the bone during sample preparation. Testing was therefore not possible in this group. Porous implants showed macroscopic integration and breaking point at implant surface. We measured a median Ultimate Shear Strength of 0,06 MPa (IQR:1,14), a median Apparent Shear Stiff ness of 0,16 MPa/mm (IQR:0,48) and a median Energy Absorption of 19,98 J/m2 (IQR:25,80).

Conclusion
Our study shows superior osseointegration in 3DP implants with a porous surface

#89: Significantly poorer survival in irradiated breast cancer patients with estrogen receptor negative and low tumor-infiltrating lymphocytes (TILs) tumors, a DBCG study

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Abstract
Background
Previous studies of a large national Danish cohort of breast cancer (BC) patients revealed that high levels of tumor-infiltrating lymphocytes (TILs) in treatment-naïve tumor tissue predicts improved overall survival (OS) after adjuvant radiotherapy (RT), especially in estrogen receptor (ER) negative tumors (ER-). The association has later been shown to be mediated through distant tumor control. We aimed to validate these findings in modern treated irradiated BC patients with varying risk profiles.

Methods and materials
Treatment-naïve tumor tissue from 1329 irradiated BC patients from two Danish Breast Cancer Group (DBCG) cohorts; high-risk BC patients (DBCG-IMN2) and low-risk BC patients (DBCG-HYPO) were analyzed for stromal TILs using international guidelines. Endpoints included loco-regional recurrence (LRR), distant metastasis (DM), and OS.

Results
Patients were categorized into "low" and "high" TILs groups using a 30% cutoff. In the high-risk DBCG-IMN2 cohort, ER-/low TILs tumors showed significantly worse OS after RT compared to ER-/high TILs (Hazard ratio (HR) 0.35 (95% CI: 0.21-0.58)) with an absolute decrease in OS at 10-years of 29.4% for ER-/low TILs tumors. No significant difference in OS was observed in ER+ tumors (HR 1.02 (0.68-1.55)). Interaction test between ER-status and TILs was significant ($p<0.001$). A similar association was found for DM (HR 0.36 (0.20-0.63)), where ER-/low TILs tumors had a higher risk (10-year increase of 24.1%) compared to ER-/high TILs. TILs did not impact loco-regional control in ER- tumors (HR=0.87 (0.28-2.67)). Similar trends were observed in the low-risk DBCG-HYPO cohort.

Conclusions
The study validates previous findings, indicating a robust association between TILs and ER-status in irradiated BC patients with diverse risk profiles. Importantly, it suggests that superior OS in irradiated patients with high TILs is likely mediated through distant tumor control rather than improved local control.

#90: Machine learning for prediction of 30-day mortality in patients with advanced cancer

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Abstract
Introduction
Patients near end-of-life (EOL) are unlikely to obtain survival or palliative benefits within 30 days of SACT treatment. SACT is associated with short-term side-effects compromising health-related quality of life. Thus, short-term mortality estimates are important to ensure ideal treatment interventions near EOL. The aim of this study is to apply machine learning to identify 30-day mortality in pan-cancer to support clinical decision making to ordinate SACT and thus limit late use of SACT, minimizing healthcare costs, and improving health-related quality of life near EOL.

Materials and methods
At Aalborg University Hospital we have gathered a real-world cohort of clinical data of 9851 patients with advanced cancer in contact with the Department of Oncology at the North Jutland Region, between January 1, 2008, and December 31, 2022. The cancer types include urinary, prostate, uterine, ovarian, colorectal, pancreatic, gastroesophageal, breast, lung, and brain cancer. The study includes a wide range of clinical variables, which will be used in state-of-the-art machine learning models for tabular data, including Elastic Net Regression and eXtreme Gradient Boosting. Furthermore, performance between general and cancer specific machine learning models will be compared.

Results
Preliminary results demonstrate the feasibility of predicting 30-day mortality across cancer types. ROC AUC of the cancer specific models varied on the held-out test data from 0.76 for brain cancer to 0.92 for ovarian cancer. The project is ongoing, and final results will be presented on the poster.

Conclusion
Based on the preliminary results, it is expected that the use of state-of-the-art machine learning models can predict short-term mortality in advanced cancer patients using a wide range of clinical variables. These models could be used as decision support, guiding SACT, but more work will be needed to bring it to the clinic.

#91: Towards personalized radiotherapy for pancreatic cancer using longitudinal diffusion MRI

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Abstract
Introduction
The hybrid MRI linear accelerator (MRI-linac) has made stereotactic body radiotherapy (RT) of pancreatic cancer (PC) feasible, thanks to daily plan adaptations based on the anatomy of the day. However, the lack of local control in some patients indicates that further optimization is needed. This might be sought through a personalization of RT based on biological information from diff usion-weighted MRI (DWI), a promising response biomarker. As the national center for RT with curative intent for PC, Odense University Hospital collaborates with centers worldwide through the MOMENTUM study (clinicaltrials.gov NCT04075305), which has resulted in the collection of data from nearly 300 PC patients across centers. This gives optimal conditions for studying DWI as a biomarker in PC. Here, results from a single-centre pilot-study investigating the prognostic value of DWI in PC are presented, and future perspectives are provided.

Materials and methods
Forty-five patients with locally advanced PC or local recurrence in the pancreas received 5x10Gy on a 1.5T MRI-linac. DWI parameter values within the GTV at fraction one and longitudinal changes of the parameters during RT were included in the analysis, as well as standard clinical parameters. A cox proportional hazards model was made with overall survival (OS) as the endpoint, based on best sub-set selection using cross-validation.

Results
The best model for OS included only two parameters, both derived from DWI, representing information from fraction one and DWI changes during the RT course, respectively. The model demonstrated capability to discriminate between patients with a long and short survival time. Noticeably, none of the clinical parameters showed any statistically significant association with OS.

Conclusions
DWI indicated value in the prediction of OS in PC. Based on the findings, a multi-center validation study of DWI as a biomarker in PC has been initiated, utilizing data from the MOMENTUM study.

#92: Longitudinal magnetic resonance elastography detects stiff ness changes in post-operative brain tumor patient

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Abstract
Introduction
After surgery and radiochemotherapy, glioma patients are followed with serial magnetic resonance imaging (MRI) scans. The follow-up may be complicated by the occurrence of pseudoprogression, which mimics true disease progression on contrast-enhanced MRI, but requires a different treatment approach. Magnetic resonance elastography (MRE) is a new imaging technique that may be able to discern pseudoprogression from true progression, as it gives quantitative information about tissue stiff ness, similar to manual palpation. Here, we report on the first use of longitudinal MRE in a patient and its potential to detect stiff ness changes in contrast-enhancing lesions during MRI follow-up.

Materials and methods
This is an ongoing case study, where a patient treated for a IDH1 mutated astrocytoma WHO grade 4 has been imaged with the standard MRI protocol and MRE for the past thirteen months. During this period, the patient developed contrast-enhancement adjacent to the operation cavity. Stiff ness is measured in three regions of interest (ROI) in the contrast-enhancing area. ROIs are also delineated in the anatomical locations where contrast enhancement appeared on later scans. Additionally, stiff ness is recorded in normal-appearing white matter in the contralateral hemisphere.

Results
Stiff ness is lower in the contrast-enhancing area compared to the contralateral hemisphere throughout the follow-up period (mean 2.14 kilo pascals (kPa) vs. 3.07 kPa, $p < 0.0001$). In two ROIs, stiff ness first increases up to the point when the contrast enhancement appears. In the third ROI, stiff ness continuously decreases throughout follow-up. In all ROIs, stiff ness tends to decrease as contrast enhancing area increases.

Conclusion
MRE can detect stiff ness changes prior to and after contrast enhancement develops. Further MRE and follow-up data is needed before drawing conclusions about the nature of the contrast-enhancing area and implementing MRE in the clinical routine.

#93: Rethinking the Elective Target Volume: Modelling Lymphatic Micrometastasis for Personalised Treatment of Head and Neck Squamous Cell Carcinoma

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Abstract
Introduction
In radiotherapy for head and neck cancer (HNC), we treat lymph nodes (LN) that are at risk of harbouring metastatic cancer (MC) - the elective clinical target volume (CTVe). Although the dose to the CTVe is relatively low, it covers a large volume, increasing the risk of radiation induced side effects. This study introduces a new probabilistic approach to tailor the CTVe for each patient, including only high-risk LN to minimise the volume of irradiation.

Materials and methods
In this study, we used a probabilistic framework to estimate the likelihood of LN containing MC in patients with HNC. One model addressed early-stage (ES) tumours and another advanced-stage (AS), considering lymph node levels (LNL) I, II, III & IV. Our criteria for including a LNL in the CTVe was ≥10% likelihood of harbouring MC, based on our models. We analysed 428 patients with central oropharyngeal tumours, using 275 for the ES-model and 153 for the AS-model. We compared the model-based CTVe with the clinical-used CTVe in a random sample of 50 patients.

Results
We observed that ipsilateral LNL II is most likely to have MC, regardless of the tumour's stage. Therefore, LNL II should always be included in the CTVe. If there are no malignant LNs either ipsilaterally and/or contralaterally, treatment can be limited to ipsilateral LNL II only, regardless of the tumour's stage. Comparison between the model-based CTVe and clinical CTVe showed substantial differences, with the clinical CTVe demonstrating larger volumes compared to the model-based approach.

Conclusion
In this study, we demonstrated that through risk-based assessment for the inclusion LNL in the CTVe, we can achieve a reduction in treatment volumes compared to current clinical practices. Our findings suggest that rethinking current guidelines to include volume-deescalated radiotherapy, could reduce unnecessary irradiation, leading to fewer severe side effects and better quality of life on individual patient basis.

#94: Bonesparing radiotherapy for anal cancer. Plan comparison in the DACG II trial

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Abstract
Purpose
Pelvic insuffi ciency fracture (PIF) is a well-known late eff ect after radiotherapy for anal cancer. Based on previous data, describing localization of PIFs and relation to radiation dose, the prospective phase II trial: Bone-sparing chemoradiotherapy for anal cancer (Danish Anal Cancer Group, DACG II) was initiated. Here we present data from the bone optimized dose planning.

Material and methods
Patients treated with standard chemoradiotherapy for anal cancer were included. Target and elective volumes were delineated according to DACG guidelines. Standard organs at risks (OARs) included bowel bag, bladder, femoral heads, genitalia and sacral bone. Further, remaining normal tissue (RNT: Body minus PTVs and delineated OARs) was evaluated. Pelvic bone substructures (PBS) included: sacroiliac (SI)- joints L (left) and R (right), sacral alae L/R, acetabulum L/R, symphysis L/R, and total pelvic bones. First, a plan fulfilling standard criteria was generated then it was optimized for PBS. Bone optimization criteria were: V30Gy<55% for PBS and comparable target coverage and dose to other OARs. A paired t-test was used for comparison and $p<0.05$ considered statistically significant. Here we report mean[SD] from high priority PBS and OARs.

Results
A total of 78 VMAT based bone sparing plans were compared to 78 standard plans. Dose to CTV-Tumor and Node was 54-60 Gy and elective dose 48 Gy, all in 30 fractions. V30Gy(%) to SI-joints L/R were reduced from 45 [16] to 31 [11] and 44 [16] to 30 [10]. For sacral ala L/R from 67 [22] to 52 [18] and from 66 [23] to 52 [19], all $p<0.0001$. Total pelvic bones V15Gy(%) and V30Gy(%) were also significantly reduced, $p<0.0001$. Dose to bowel bag V15Gy(cc), V30Gy(cc), V45Gy(cc), bladder V35(%), RNT V15Gy(%)-V45Gy(%) were comparable or better with bone sparing plans.

Conclusion
We demonstrate that significant sparing of PBS is feasible with optimization standard plans with-out compromising target coverage or dose to other OARs.

#95: Expression of cancer stem cell markers as potential biomarker in squamous cell carcinoma of the anus

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Abstract
Introduction
Cancer stem cells (CSCs) are thought to play an important role in radioresistance as these cells hold the potential to differentiate into viable cancer cells. Hence, all CSCs need to be eradicated to achieve permanent local tumour control after radiotherapy. As the majority of failures in squamous cell carcinomas of the anus (SCCA) are observed at the primary tumour site, CSC markers could be highly relevant biomarkers. This study aimed to evaluate the prognostic value of the expression of the potential CSC markers, MET and SLC3A2, in SCCA.

Materials and methods
Formalin-fixed paraffin-embedded diagnostic biopsies from patients diagnosed with SCCA between 1998-2018 and treated with (chemo)radiotherapy were collected and RNA extracted. The expression of MET and SLC3A2 were analysed by quantitative real-time polymerase chain reaction (qPCR). Cumulative incidence was estimated by the Kaplan-Meier estimator (disease-free survival), and hazard ratios (HR) were obtained using Cox regression. Bootstrap analysis was performed on each of the individual Cox analyses to identify the most optimal cutoff point for MET and SLC3A2.

Results
From 357 successfully performed qPCR analyses, MET expression analysis was successful in 326 cases and SLC3A2 expression in 340 cases. The estimated cutoff point for MET was -4.90, and -4.00 for SLC3A2. In univariate analysis, patients with a MET expression value above the cutoff point had a significantly higher risk of treatment failure compared to patients with a value below the cutoff (HR = 2.46 (1.35, 4.48), p = 0.002). The same was seen for SLC3A2 (HR = 1.89 (1.27, 2.81), p = 0.001). In multivariate analysis, both CSC markers remained significant (MET, HR = 2.96 (1.58, 5.53), p = 0.001 and SLC3A2, HR = 1.88 (1.26, 2.81), p = 0.002).

Conclusions
The potential CSC markers, MET and SLC3A2, were prognostic for outcome in SCCA. These markers could be important for future radiotherapeutic treatment stratification in SCCA.

#96: Pre-treatment immune-inflammation-related biomarkers and relation to disease-free survival in anal cancer

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Abstract
Introduction
Cancer development is highly correlated to the immune system, and inflammation is one of the hallmarks of cancer. Hence measurement of neutrophile-lymphocyte ratio (NLR), platelet-lymphocyte ratio (PLR) and systemic inflammatory index (SII) in pre-treatment blood samples have been proposed as easy-to-measure biomarkers related to the prognosis of different cancer types, including anal cancer (AC). This study aimed to investigate if these biomarkers were prognostic for disease-free survival (DFS) in AC.

Material and methods
From pre-treatment blood samples of 339 patients with AC treated with curative (chemo)radiotherapy, the NLR, PLR and SII (platelet x neutrophil/lymphocyte) were calculated. The most optimal cut-off values for NLR, PLR and SII were estimated by computing receiver operating characteristic (ROC) curves and the area under the curves (AUC) using the method by Liu. The primary endpoint was DFS, estimated by the Kaplan-Meier method.

Results
AUC for NLR was 0.63, and the best cut-off value was 2.98 (sensitivity 62 %, specificity 73 %). The AUC for PLR was 0.57 with a cut-off value of 145.31 (sensitivity 56 %, specificity 60 %), and the AUC for SII was 0.62 with a cut-off value of 679.86 (sensitivity 66 %, specificity 55 %). DFS was significantly worse in patients with values above the calculated cut-off for all three biomarkers, with a hazard ratio (HR) of 2.08 (95%CI 1.51;2.85), p<0.001 for NLR, 1.85 (95%CI 1.34;2.54), p<0.001 for PLR, and 2.13 (95%CI 1.53;2.96), p<0.001 for SII. In multivariate cox regression analysis, NLR stayed significant for DFS (HR = 1.55 (95%CI 1.03, 2.34) p = 0.035).

Conclusions
All three immune-inflammation-related markers were prognostic for DFS in AC. These easy-to-measure biomarkers could be relevant, potentially in combination with other emerging biomarkers, and international collaboration would be highly relevant in future investigations.

11. Personalized medicine, biomarkers & diagnostics II #97-106

#97: Preoperative ctDNA, the tumor microenvironment and the risk of recurrence in non-metastatic colorectal cancer

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Abstract
Introduction
Recurrence after curative-intent surgery for colorectal cancer is a major cause of cancer-related death. Circulating cell-free tumor DNA (ctDNA) is increasingly being used in the perioperative setting to measure disease burden and detect residual disease. However, the association between preoperative ctDNA, the tumor microenvironment, including tumor-infiltrating lymphocytes, and recurrence is unknown.

Materials and methods
In this Danish cohort study, we included patients who underwent curative-intent surgery for localized colorectal cancer between 2016 and 2019 at Slagelse Hospital. Preoperative ctDNA detection was assessed via a blood-based methylation marker test, tumor-infiltrating lymphocytes was countifi ed via immunohistochemistry and a digital app, while the tumor microenvironment was investigated via a mRNA expression-based approach. The aim was to investigate if ctDNA was associated with the tumor microenvironment and if it could identify specifi c phenotypes of patients that later experienced recurrence.

Results
Among 140 patients, ctDNA tested positive in 102 (72.9%) before surgery, with 38 (27.1%) tumors classifi ed as immune infi ltration high. ctDNA levels were inversely correlated with immune infi ltration (correlation coeffi cient -0.93, p.adj < 0.001), with ctDNA variables being ranked high in elastic net regression models with recurrence as an outcome. Further, signifi cant associations were found between cancer-metastasis pathways and ctDNA positivity. Conclusions Our results suggest that the tumor microenvironment could be predicted by a preoperative blood-based tumor-agnostic ctDNA test.

#98: Using a clinicopathologic and gene expression model (CP-GEP) to predict prognosis in stage I-II primary cutaneous melanoma: a multicenter Danish cohort study

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Abstract
Introduction
Melanoma patients without sentinel node (SN) metastasis (stage I-II) constitute a remarkably heterogeneous group regarding recurrence and survival. While adjuvant immunotherapy for stage IIB-C melanoma has gained approval from FDA and EMA, its use can lead to severe adverse effects and financial strain on healthcare systems. There is a need for new diagnostic approaches to more precisely identify early-stage melanoma patients at high risk of recurrence who could benefit from adjuvant treatment and intensified surveillance. The clinicopathological and gene expression profile model (CP-GEP), initially developed to predict SN metastasis, has demonstrated promise in stratifying stage I-II melanoma patients into high and low risk of recurrence. This study aimed to validate the prognostic utility of the CP-GEP in a Danish cohort of stage I-II melanoma patients.

Materials and methods
Archived primary melanoma tissue from 438 T1-T3 cutaneous melanoma patients with negative SN biopsies (stage I-II) performed between 2010 and 2015 at two university clinics in Denmark was collected and analysed with CP-GEP. CP-GEP combines Breslow thickness and patient age with the expression of eight genes in the primary tumor, stratifying patients into high or low risk of recurrence. The primary outcome was 5-year recurrence-free survival (RFS), with 5-year overall survival (OS) as secondary outcome.

Results
CP-GEP stratified 199 patients as low-risk and 239 as high-risk. The low-risk group demonstrated a 5-year RFS of 92.0% (95% CI: 87.2-95.0) compared to 82.8% (95% CI: 77.4-87.1) in the high-risk group (HR 1.75 (95% CI: 1.13-2.72)). The 5-year OS was 92.5% (95% CI: 87.8-95.4) for the low-risk group vs. 86.6% (95% CI: 81.6-90.3) for the high-risk group (HR 1.65 (95% CI: 1.05-2.59)).

Conclusion
CP-GEP can stratify stage I-II melanoma patients into high and low risk for recurrence, indicating its potential value in treatment decision-making and surveillance strategies.

#99: CDCA2 promotes cellular proliferation and bortezomib sensitivity in diffuse large B-cell lymphoma

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Abstract
Introduction
Numerous clinical trials have attempted to improve first-line R-CHOP treatment of diffuse large B-cell lymphoma (DLBCL) through addition or substitution of drugs. The REMoDL-B trial testing R-CHOP versus R-CHOP + bortezomib (RB-CHOP) in DLBCL patients stratified by molecular subgroup revealed that molecular high-grade patients benefit from bortezomib addition. The aim of this study was to obtain better understanding of bortezomib response in DLBCL by functional investigation of clinical identified markers.

Materials and methods
Data from the REMoDL-B trial was retrospectively analyzed by fitting a multivariate Cox regression testing all expressed genes with overall survival as outcome and an interaction term between gene expression and treatment arms. The top candidate, CDCA2 was functional investigated by applying CRISPR/Cas9 in DLBCL cells.

Results
DLBCL patients with high expression of CDCA2 have superior outcome when treated with RB-CHOP in comparison to R-CHOP (p=0.0097), whereas no difference in outcome was observed for patients with low CDCA2 (p=0.086). Knockout of CDCA2 decreased proliferation in DLBCL cells and in xenograft mouse models. Bortezomib dose-response analysis revealed reduced sensitivity in CDCA2 knockout cells compared to the control. In combinatory drug experiments comparing CHOP and B-CHOP, CDCA2 knockout cells demonstrated higher relative resistance compared to controls cells when exposed to B-CHOP than CHOP, illustrating CDCA2 to be cardinal and specifically mediating the bortezomib response. Gene set enrichment analysis and PI3K pathway inhibition studies illustrate involvement of the PI3K/AKT pathway in the CDCA2 driven bortezomib response.

Conclusion
This study shows that DLBCL patients with high expression levels of CDCA2 benefitted the most from addition of bortezomib to R-CHOP. Functional studies documented a direct impact of CDCA2 on bortezomib response in DLBCL cells, including regulation by the PI3K pathway.

#100: Next-level cancer staging through growth rate assessment

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Abstract
Introduction
Treatment decisions in cancer care often rely on staging systems to determine the extent of disease development. Yet, conventional staging methods, like the TNM system, only offer a static snapshot of the disease, lacking dynamic insights into advancement pace. Adding information on disease growth rates could enhance clinical decision-making. Quantifying circulating tumor DNA (ctDNA) in the blood holds potential for dynamic monitoring. Here, we explore using serial ctDNA measurements in recurrence patients for assessing disease growth rates.

Materials and methods
Serial plasma samples (8mL) were collected after end of treatment from 685 stage I-III colorectal cancer patients. The ctDNA levels were measured using either digital PCR targeting a single clonal variant or ultradeep sequencing of 16 tumor-specific variants. Growth rates were assessed by log-linear regression of ctDNA levels over time and categorized as ‘fast’ or ‘slow’ by a threshold of 50% growth per month.

Results
Of the 685 patients, 91 experienced recurrence. Of these, ctDNA was detected in consecutive plasma samples in 51 patients, enabling growth rate analysis. Fast growth rates were associated with shorter survival (HR = 3.6, 95%CI = 1.4-8.9, P=0.0061) and an increased risk of developing metastases at multiple sites (OR = 5.2, 95%CI = 1.3-20, P=0.024). In a multivariable model including pathological staging, a fast growth rate was the factor most prognostic for survival (HR = 3.3, 95%CI = 1.3-8.4, P=0.0097).

Conclusions
The ctDNA growth rates offers a direct measure of disease advancement over time and a fast growth rate was associated with a more aggressive phenotype. Compared to the still-image provided by TNM staging today, ctDNA growth rates were more prognostic for survival. These findings suggest the potential for growth rates to serve not only as prognostic indicators but also as predictive tools for determining optimal timing of clinical interventions in cancer management.

#101: Circulating Tumor DNA and Risk of Recurrence in Patients with Asymptomatic versus Symptomatic Colorectal Cancer

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Abstract

Background
Circulating tumor DNA (ctDNA) analysis has gained prominence for cancer detection and multiple initiatives are striving to develop ctDNA-based early detection tests. However, most ctDNA tests have only been evaluated in symptomatic patients. The few studies describing ctDNA testing in asymptomatic patients all report lower ctDNA detection rates. This raise the question if asymptomatic patients differ from symptomatic patients e.g. by including a low-ctDNA-shedding and less aggressive subgroup? Here, we addressed this critical question focusing on colorectal cancer.

Methods
A tumor-agnostic methylation-based approach was used for ctDNA assessment in plasma from 215 asymptomatic and 117 symptomatic CRC patients. For validation, an orthogonal tumor-informed approach was applied on plasma from 368 asymptomatic and 722 symptomatic CRC patients.

Results
The ctDNA detection rate was 50% in asymptomatic and 82% in symptomatic CRC patients. After adjusting for tumor stage and size, the odds of detecting ctDNA was significantly lower in asymptomatic patients compared to symptomatic patients in both cohorts (OR:0.3, 95% CI: 0.1-0.6 and OR:0.7 95%CI: 0.5-0.9). Additionally, asymptomatic patients had a substantially lower recurrence risk compared to symptomatic patients (HR: 0.6, 95%CI: 0.3-1.2). Stratifying the asymptomatic patients according to ctDNA status revealed that ctDNA-negative patients had the lowest recurrence risk (HR: 0.2, 95%CI: 0.1-0.5), while the risk of ctDNA-positive patients was comparable to that of symptomatic patients.

Conclusions
Our study suggests that asymptomatic patients differ from symptomatic patients by having tumors characterized by a ‘low-ctDNA-shedding’ phenotype and by having lower risk of recurrence. These insights could guide the expectations of initiatives exploring ctDNA approaches for early cancer detection and could prompt discussions about de-escalation of therapy and follow-up for ctDNA-negative asymptomatic patients.

#102: The diagnostic value of C-reactive protein, lactate dehydrogenase, and hemoglobin in a high-risk cohort undergoing diagnostic workup for lung cancer

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Abstract
Introduction
Lung cancer is the leading cause of cancer related death in Denmark, partly because lung cancer is often diagnosed in an advanced stage. Biomarkers may be useful for early detection. We aimed to analyze a wide variety of biomarkers in blood and bronchial lavage samples for lung cancer detection, and here we present the preliminary analyses of the standard blood analyses.

Materials and methods
Patients were referred for diagnostic workup on suspicion of lung cancer. The diagnostic procedures included chest and abdominal computed tomography scan, bronchoscopy, blood tests, and histopathological or cytological verifi cation. The blood analyses for C-reactive protein (CRP), lactate dehydrogenase (LDH), and hemoglobin (HGB) were performed according to standard practice.

Results
A total of 265 patients were recruited from five Danish centers from August 2020 to November 2023. The median age was 71 years (interquartile range, IQR 62-77), 45% were female, and 66% were diagnosed with lung cancer, while 3% were diagnosed with cancer of another origin. The median levels of CRP, LDH, and HGB were 5 mg/L (IQR 3-22), 210 units/L (IQR 179-244), and 8.5 mmol/L (IQR 7.7-9.2), respectively. A CRP >=10 mg/L was signifi cantly associated with a diagnosis of lung cancer (n=228, p<0.001), while LDH >=230 units/L or HGB <=7.8 mmol/L were not (p>0.05). A multiple logistic regression model including all three blood analyses (n=157) resulted in an odds ratio for CRP of 3.77 (95% confi dence interval 1.56-9.13, p=0.003), and the area under the logistic regression receiver operating characteristics curve was 0.64.

Conclusions
An elevated level of CRP >=10 mg/L was signifi cantly associated with being diagnosed with lung cancer, but the diagnostic value of a logistic regression model based on three commonly used blood analyses was very limited. Novel biomarkers such as circulating tumor DNA or plasma metabolites may be able to improve the diagnostic accuracy of blood tests.

#103: Circulating tumor DNA guided treatment monitoring in advanced lung cancer - a randomized interventional study

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Abstract
Background
Monitoring treatment efficacy in patients with advanced non-small cell lung cancer (NSCLC) treated by Immune Checkpoint Inhibitors (ICI) is routinely done by imaging and coherent RECIST criteria. Recent data indicate that monitoring by liquid biopsy could be a promising new alternative or supplement.In this non-inferior study design, we aim to investigate if circulating tumor DNA (ctDNA) evaluation can reduce the numbers of inefficient ICI treatments without reducing Overall Survival (OS) in patients with advanced NSCLC treated by first line ICI.

Materials and methods
PRELUCA is a multicenter randomized, interventional study, which aims to enroll 350 patients with advanced NSCLC, receiving first-line ICI. Patients are randomized in a 1:1 ratio to either evaluation by ctDNA measurements (digital droplet PCR) before every treatment cycle or standard evaluation by CT scans every 3rd treatment cycle (iRECIST). QoL questionnaires (QLQ-30 and LC13) and CTC adverse events registration are performed prior to every treatment cycle. ICI treatment is discontinued after 6 months if ctDNA-RECIST complete response (CR) is observed for patients in the ctDNA evaluation arm, and patients will be followed by ctDNA measurements every 4th week.

Results and conclusion
30 patients have been enrolled at hospitals in Roskilde, Næstved, Vejle and Aalborg.The primary endpoint is OS, and secondary outcomes include number of treatments, adverse events, and progression free survival (PFS).If the study outcome is shown to be non-inferior, then ctDNA measurements could become a new clinical tool to evaluate ICI treatment with the possibility to reduce numbers of inefficient ICI treatments, adverse events, and ultimately improve QoL and cost-effectiveness.

#104: Circulating Tumor DNA for Assessing Neoadjuvant Treatment Response and Recurrence Risk in Rectal Cancer Patients

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Abstract
Introduction
Disease recurrence after surgery is the main factor affecting survival in rectal cancer patients. Hence, identifying high-risk patients is important to optimize postsurgical treatment. In recent years, effective use of neoadjuvant therapy (NAT) have led to increased focus on non-operative “watch-and-wait” strategies. However, clinical modalities for assessing complete response following NAT are not sufficiently accurate for selecting patients suitable for non-operative management. Biomarkers such as circulating tumor DNA (ctDNA) offers great potential for predicting neoadjuvant treatment response and identifying patients at risk of recurrence.

Materials and methods
We recruited 114 patients with locally advanced rectal cancer treated with NAT and surgery. Plasma samples (n=319) were collected before therapy, after neoadjuvant therapy, and postoperatively. Analysis of ctDNA was performed using a tumor-agnostic droplet digital PCR test targeting three methylation markers.

Results
The pre-treatment ctDNA detection rate was 86.8%. Post-NAT ctDNA status was significantly associated with pathologic complete response (pCR; p=0.03, Fisher’s exact). None of the 11 patients with pCR had ctDNA detected following NAT and the sensitivity for detecting residual disease was 32%. Detectable ctDNA was associated with worse recurrence-free survival (RFS) and overall survival (OS), both after NAT (RFS HR 3.2, 95%CI 1.5-6.8, p=0.004; OS HR 3.0, 95%CI 1.1-8.4, p=0.03) and after surgery (RFS HR 8.3, 95%CI 3.7-18.9, p<0.001; OS HR 10.6, 95%CI 3.4-33.4, p<0.001).

Conclusions
In conclusion, we showed that ctDNA status after NAT was significantly associated with pCR, however the sensitivity for detecting residual disease is insufficient to guide “watch-and-wait” strategies. Thus, additional studies are needed. Moreover, our study demonstrated the prognostic value of ctDNA analysis in predicting recurrence and survival outcomes in neoadjuvant-treated rectal cancer patients.

#105: Comprehensive characterization of the T cell receptor repertoire in bladder cancer

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Abstract
Introduction
Cancer-specific T cells can recognize cancer neoantigens through their receptors (TCRs). Their expansion is believed to be an early response to malignancy. We hypothesized that the T cell landscape could off er insights into immune competency and aimed to characterize the TCR repertoire in patients with bladder cancer (BC) and explore correlations with disease outcome.

Materials and methods
We analyzed the TCR landscape in blood and tumor samples from 119 patients with muscle-invasive BC using ultradeep amplicon-based sequencing of the TCR-b chain. Overall T cell fractions were inferred from whole exome sequence data of blood DNA. The T cell subtype composition in tumor and blood was investigated in four patients using the Chromium Single Cell kit from 10X Genomics.

Results
Low peripheral TCR diversity was associated with a worse outcome in BC, particularly when combined with a low fraction of circulating T cells. These repertoires were characterized by large, expanded T cell clones that persisted over time. Longitudinal analysis indicated a potential adverse impact of treatment, evidenced by a reduction in TCR diversity and circulating T cells over time in patients with initially high-diversity repertoire. We observed a notable disparity between tumor and peripheral blood TCR repertoires. Single-cell sequencing revealed that regulatory T cells were prevalent in the tumor, whereas cytotoxic and naïve T cells dominated the blood. More explicitly, expanded clones in the blood were mostly annotated as effector memory T cells expressing high levels of cytotoxic and exhausted genes.

Conclusion
We suggest that high TCR diversity and T cell fraction are markers of general immune competence, reflecting the ability to combat cancer and other diseases. Our findings underline the crucial role of the immune system in determining disease outcomes and highlight the potential for improving immune health as a promising approach for future treatment and prevention.

#106: High expression of the exhaustion markers PD1 and PD-L1 in non-muscle invasive bladder cancer is associated with poor outcome following Bacillus Calmette-Guérin immunotherapy

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Abstract
Introduction
The recommended treatment of high-risk non-muscle bladder cancer (NMIBC) is intravesical instillations of Bacillus Calmette-Guérin (BCG). However, 40 % experience recurrence within 5 years, despite completing the BCG treatment. Here we investigated if T cell exhaustion, characterized by protein expression of PD1 and PD-L1 measured in paired samples obtained before and after BCG treatment could further explain BCG response and help predict outcome in patients with NMIBC.

Materials and methods
We included 111 patients with NMIBC, from which we had 183 TURB-T samples obtained before and after BCG treatment. Using immunohistochemistry staining of sections from tissue microarrays (TMAs) with triplicate core biopsies, we investigated the protein expression of the exhaustion markers PD1 and PD-L1. Data was analyzed using digital pathology software (Visiopharm®).In total, 167 samples from 105 patients were considered suitable for further analysis (cell count > 200 in carcinoma and stromal areas) with 2-3 cores per sample. Stratifi cation of samples into high or low expression was based on a median split of the positive cell fraction.

Results
We observed that PD-1 expression significantly increased with tumor stage in pre- (p=0.002) and post-BCG (p=0.006) tumor samples. PD-1 expression was also increased in high-grade tumors compared to low-grade tumors in pre-BCG samples (p = 0.001). Furthermore, we observed a signifi cant association between tumors of higher stage and high PD-L1 expression in the pre-BCG samples (p = 0.007).Patients with low expression of PD1 and PD-L1 in the pre-BCG tumor samples had a superior high-grade recurrence-free survival compared to patients with high PD1 (p=0.002) and PD-L1 (p=0.021) expression.

Conclusions
Protein expression of PD1 and PD-L1 in pre-BCG tumor samples were correlated to higher stage and grade as well as worse HGFRS, indicating that T cell exhaustion plays an important role in resistance to BCG treatment.