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# Protokoloversigt

## Den Kliniske Forskningsenhed Onkologisk Afdeling Aalborg Universitetshospital

Protokolregi/nummer	Kort titel/beskrivelse	Investigator/ projektsygeplejerske	Aktiveret/ (lukket)
<b>Team 1</b>			
<b>Kolorektalcancer</b>			
<b>Adjuverende</b>			
RESET-R	Immunotherapy in patients with early dMMR rectal cancer. A Danish DCCG phase II trial	LØP/sln	02/24
OxaNeuro	Prevention of oxaliplatin-induced peripheral neuropathy – a randomized controlled trial	SC/fh	11/23
RESET-C	Efficacy of immunotherapy in patients with MMR-deficient localized colon cancer scheduled for curative surgery - A prospective, phase II study	LØP/sln	05/23 (04/24)
PRECANU	Frequency and classification of acute radiation-induced diarrhoea in patients with prostate and rectal cancer during curative external radiotherapy	MY/la+moh	05/22
WW3	Randomized trial of standard dose versus high dose of radiotherapy in rectal preservation with chemo-radiotherapy to patients with early low and mid rectal cancer The Watchful Waiting 3 trial	LØP/fh	02/20
NEOLAR	Neoadjuverende kemoterapi alene sammenlignet med standardbehandling for lokalavanceret rektumcancer: et randomiseret fase II forsøg	LØP/fh	01/20
IMPROVE IT	Implementing non-invasive circulating tumor DNA analysis to optimize the operative and postoperative treatment for patients with colorectal cancer	MY/fh	11/19
NeoCol	En undersøgelse, der belyser effekten af kombinationskemoterapi før operation hos patienter med tyktarmskræft	MY/la	05/17 (12/20)
WW2	Kurativ kemostrålebehandling af lav rectumcancer. En undersøgelse, der belyser muligheden for at undgå operation efter strålebehandling og kemoterapi for kræft i endetarmen	LØP/fh	09/15 (07/16) 04/17 (12/19)

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RAPIDO	Randomiseret fase III undersøgelse. Kort strålebehandling efterfulgt af præ-operativ kemoterapi vs. lang kemo-stråleterapi efterfulgt af operation og evt. adjuverende kemoterapi som primær behandling af høj-risiko rectum cancer	LØP/fh	09/14 (05/16)
<b><u>Metastaserende</u></b>			
MK-1308A	Et forsøg hvor MK-1308A (quavonlimab og pembrolizumab) sammenlignes med andre behandlinger til patienter med en bestemt type tyk- og endetarms kræft (høj mikrosatellitinstabilitet eller mismatch repair-defekt)	LØP/mer	05/23
SEAMARK	A PHASE 2, RANDOMIZED, OPEN-LABEL STUDY OF ENCORAFENIB AND CETUXIMAB PLUS PEMBROLIZUMAB VERSUS PEMBROLIZUMAB ALONE IN PARTICIPANTS WITH PREVIOUSLY UNTREATED BRAF V600E-MUTANT, MSI-H/DMMR METASTATIC COLORECTAL CANCER	LØP/la	12/22
BREAKWATER	An open-label, multicenter, randomized phase 3 study of first-line encorafenib plus cetuximab with or without chemotherapy versus standard of care therapy with a safety lead-in of encorafenib and cetuximab plus chemotherapy in participants with metastatic braf v600e-mutant colorectal cancer	RO/la	05/22 (06/24)
NEW BEACON	Beacon regimen with cetuximab every second week. Cetuximab given every second week with encorafenib in patients with BRAFV600E mutated metastatic colorectal cancer. A Nordic phase II study.	LØP/la	11/21
SCO101-001	A Phase 2 Trial of SCO-101 in combination with FOLFIRI for Patients with Metastatic Colorectal Cancer (mCRC) with acquired Resistance to FOLFIRI	ML/la	06/20
New SPCRC	Skandinavisk forskningsprojekt for patienter med spredning fra tyk- og endetarmskræft	MY/fh	05/17 (11/19)
<b><u>Ventrikelcancer</u></b>			
<b><u>Neoadjuverende</u></b>			
CURE	The CURE study: Clinical Utility of circulating Tumor DNA in Gastro-Esophageal Cancer	ML/sln	02/24
MATTERHORN	A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients with Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC)	MY/sln	06/21 (07/22)

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<b><u>Metastaserende</u></b>			
HERES	Trastuzumab og standardbehandling med kemo- og immunterapi med pembrolizumab som første linie behandling til patienter med HER2 positiv planocellulær esofaguscarcinom	MY/fh	10/22
<b><u>Pancreascancer</u></b>			
DPCG-01	A randomized phase II study of gemcitabine versus reduced-dose combination chemotherapy in fragile patients with non-resectable pancreatic cancer	LSR/ML/fh	07/23
EarlyCarePan	Early Palliative Care for Patients with Advanced Pancreatic Cancer	ML/sln	06/22 (04/24)
SCO101-002 PANTAX	An open-label phase Ib prospective clinical trial to investigate safety, tolerability and maximum tolerated dose for SCO-101 in combination with Gemcitabine and Nab-Paclitaxel in inoperable pancreatic cancer patients	ML/mer	11/20 (02/23)
CANFOUR	An open label, dose escalation followed by dose expansion, safety and tolerability trial of CAN04, a fully humanized monoclonal antibody against IL1RAP, in subjects with solid malignant tumors	LØP/mer	06/20 (09/21)
LAPC-03	Kemoterapi (FOLFIRINOX) efterfulgt af lokal-behandling (operation, strålebehandling og/eller irreversibel elektroporation (IRE) hos patienter med lokalavanceret pancreas cancer (LAPC)	ML/mer	04/19 (06/23)
BIOPAC	Biomarkører ved Pancreas Cancer (BIOPAC) – giver de ny information om sygdommen og forbedret monitorering og prognostisering af patienterne?	MY/mer	04/10

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<b>Team 2</b>			
<b>Gynækologisk cancer</b>			
<b>Ovariecancer</b>			
KEYNOTE-B96	A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Paclitaxel With or Without Bevacizumab for the Treatment of Platinum-resistant Recurrent Ovarian Cancer (KEYNOTE-B96 / ENGOT-ov65)	CH/sln	04/22 (05/23)
DOVACC	ENGOT-OV56/NSGO-CTU-DOVACC A Randomized Clinical Trial Investigating Olaparib, Durvalumab (MEDI4736) and UV1 as Maintenance Therapy in BRCAwt Patients with Recurrent Ovarian Cancer	CH/fh	05/22
DUO-O	Et randomiseret, dobbeltblindet, placebokontrolleret Multicenter fase III-forsøg til vurdering af durvalumab i kombination med kemoterapi og bevacizumab efterfulgt af vedligeholdelsesbehandling med durvalumab, bevacizumab og olaparib hos patienter med nydiagnosticeret fremskreden ovariecancer (DUO-O)	BL/fh	08/19 (04/21)
ATHENA	Et randomiseret, dobbeltblindet, placebokontrolleret fase 3-multicenterforsøg med ovariecancerpatienter med henblik på evaluering af rucaparib og nivolumab som vedligeholdelsesbehandling efter respons på platinbaseret frontlinjekemoterapi	BL/fh	07/19 (04/20)
PRIMA	Et fase 3, randomiseret, dobbeltblindet, placebokontrolleret, multicenterforsøg med niraparib vedligeholdelsesbehandling til patienter med HRD-positiv fremskreden æggestokkræft efter respons på primær kemoterapi	BL/fh	10/16 (06/18)
<b>Endometrie-cancer</b>			
KEYNOTE-C93	A Phase 3 Randomized, Open-label, Active-comparator Controlled Clinical Study of Pembrolizumab versus Platinum Doublet Chemotherapy in Participants With Mismatch Repair Deficient (dMMR) Advanced or Recurrent Endometrial Carcinoma in the First-line Setting (KEYNOTE-C93/GOG-3064/ENGOT-en15)	AL/sln	02/23 (11/23)
KEYNOTE B-21	A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Adjuvant Chemotherapy With or Without Radiotherapy for the Treatment of Newly Diagnosed High-Risk Endometrial Cancer After Surgery With Curative Intent (KEYNOTE-B21 / ENGOT-en11 / GOG-3053)	BL/mer	04/21 (09/22)
RUBY	A Phase 3, Randomized, Double-blind, Multicenter Study of Dostarlimab (TSR-042) Plus Carboplatin-Paclitaxel Versus Placebo Plus Carboplatin-paclitaxel in Patients With Recurrent or Primary Advanced Endometrial Cancer	AL/sln	02/20 (01/21)  Part 2: 09/21 (04/22)

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ENGOT-EN2	Endometrie-cancer, randomiseret fase III studie, st. I-II, kemoterapi/observation	BL/la	02/12 (04/19)
<b><u>Cervixcancer</u></b>			
<b><u>Primære hjernetumorer</u></b>			
DTI	DTI MRI FOR RADIATION TREATMENT PLANNING IN	CH/mer	02/24
DNOG-2	Senfølger efter behandling for hjernetumorer	CH/-	04/19
<b><u>Glioblastom</u></b>			
ONC201-108	ONC201 for the Treatment of Newly Diagnosed H3 K27M-mutant Diffuse Glioma Following Completion of Radiotherapy: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study	CH/mer	09/23
GBM-002	Et fase 1b, åbent, dosisfindende forsøg af CC-90010 i kombination med temozolomide med eller uden strålebehandling hos forsøgspersoner med nyligt diagnosticeret glioblastom	CH/la	06/22 (03/23)
<b><u>Hud</u></b>			
<b><u>Malignt Melanom</u></b>			
V940-001	A Phase 3, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With High-Risk Stage II-IV Melanoma	CH/mer	04/24
IO BioTech	A Phase 3, multicenter, international, open-label, randomized, 2-arm trial investigating the safety and efficacy of IO102-IO103 in combination with Pembrolizumab	CH/mer	02/23 (11/23)
RELATIVITY	A Phase 3, Randomized, Double-blind Study of Adjuvant Immunotherapy with Relatimab and Nivolumab Fixed-dose Combination versus Nivolumab Monotherapy after Complete	CH/mer	07/22 (11/22)

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<b><u>Team 3</u></b>			
<b><u>Lungecancer</u></b>			
NAVIGATE	Improving survival in vulnerable lung cancer patients through individual support: a multicenter randomized controlled trial	TM/cb	07/24
SCLC-OMICS	Proteins in Circulating Tumor-derived Extracellular Vesicles in Small Cell Lung Cancer	WS/abd	05/23
MonAlec	Undersøgelse af cirkulerende tumor DNA hos NSCLC-patienter behandlet med alectenib	TM/ljs	01/20
<b><u>Kurativ</u></b>			
HERAN2	Strålebehandling ved kræft i lungerne Heterogen, hypofraktioneret strålebehandling til lokalt-avanceret ikke små celledet lungekræft	WS/ljs	11/23
ACHILES	A randomized phase II study comparing atezolizumab after concurrent chemoradiotherapy with chemoradiotherapy alone in limited disease small-cell lung cancer	TM/abd	08/19 (09/21)
<b><u>Metastaserende</u></b>			
STRICT-LUNG	STEREOTACTIC RADIATION THERAPY IN CENTRALLY LOCATED LUNG TUMORS & STEREOTACTIC DAILY ADAPTED RADIATION THERAPY IN ULTRA CENTRALLY LOCATED LUNG TUMORS (STRICT & STAR-LUNG STUDY) DOLG study 0121  A multicenter phase II study of stereotactic radiotherapy for centrally located lung tumors (STRICT-LUNG STUDY) and ultra-centrally located lung tumors using daily adaptive photon therapy (STAR-LUNG STUDY)	WS/cb	07/24
MK-2870-007	A Randomized, Open-label, Phase 3 Study of MK-2870 in Combination With Pembrolizumab Compared to Pembrolizumab Monotherapy in the First-line Treatment of Participants With Metastatic Non-small Cell Lung Cancer With PD-L1 TPS Greater than or Equal to 50%	TM/ljs	07/24
HERAN1	Heterogeneously Hypofractionated Radiotherapy for Locally Advanced NSCLC An open Non-Randomised multicentre phase II feasibility study	WS/ljs	03/24
PRELUCA	Circulating tumor DNA guided treatmentmonitoring in advanced lung cancer - a randomized interventional study	WS/ljs	02/24

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LAGOON	A Randomized, Multicenter, Open-label, Phase III Study of Lurbinectedin Single-Agent or Lurbinectedin in Combination with Irinotecan versus Investigator's Choice (Topotecan or Irinotecan) in Relapsed Small Cell Lung Cancer (SCLC) Patients	WS/ljs	09/23
NIPU	Nivolumab and ipilimumab +/- UV1 vaccination as second line treatment in patients with malignant mesothelioma (the NIPU-study)	WS/ljs	01/21 (01/23)
PARAT	PAlliative RAdioTherapy to lung cancer. A randomized multicentre phase III study	SK/abd	12/19

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<b>Team 4</b>			
<b>Mammacancer</b>			
<b>Adjuverende</b>			
HER2BIC	A national randomized non-inferiority trial: Imaging versus cardiac biomarker monitored HER2 directed therapy in patients with breast cancer	MLHM/ljs	04/23
PROTON	The DBCG PROTON Trial. Adjuvant breast proton radiation therapy for early breast cancer patients: The Skagen Trial 2, a clinically controlled randomised phase III trial	MM/cb	06/22
MASTER	The MASTER study (MAMmary cancer STatin ER positive study) A Randomized, placebo-controlled, Phase III Study of (Neo)Adjuvant Atorvastatin Therapy in Patients with Early Breast Cancer	SY/lgs+abd	05/22
EPIK-B5	EPIK-B5: A Phase III, randomized, double-blind, placebocontrolled study of alpelisib (BYL719) in combination with fulvestrant for men and postmenopausal women with HRpositive, HER2-negative advanced breast cancer with a PIK3CA mutation, who progressed on or after aromatase inhibitor and a CDK4/6 inhibitor	SY/ljs	05/22
NATURAL	DBCG RT Natural studiet: Delbryst versus ingen bestråling til kvinder ≥ 60 år opereret med brystbevarelse for tidlig brystkræft, et klinisk kontrolleret randomiseret fase III studium	MM/cb	06/20
MonarchE	Et randomiseret fase 3 forsøg med Abemaciclib i kombination med standard adjuverende antihormonbehandling og standard antihormonbehandling alene efter operation for østrogen-receptor positiv og HER2-negativ brystkræft med spredning til regionale lymfeknuder.	TL/abd	08/17 (03/19)
Skagen	Strålebehandling med to forskellige doseringer til patienter opereret for brystkræft	TL/cb	07/16 (06/21)
Aphinity	Fase III. Et randomiseret, dobbeltblindet, placebokontrolleret multicenterforsøg til sammenligning af kemoterapi plus trastuzumab plus placebo med kemoterapi plus trastuzumab plus pertuzumab som adjuverende behandling hos patienter med operabel, HER2-positiv, primær brystcancer	AL/lr	06/12 (07/13)
DBCG/CIRRO RT Hypo	Fase II. Hypofraktioneret versus normofraktioneret helbrystbestråling. Registrering af morbiditet	LS/cb	09/09 (03/14)
DBCG/CIRRO RT PBI	Fase II. Delbrystbestråling versus helbrystbestråling. Registrering af morbiditet	LS/cb	09/09 (03/16)

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<b>Neoadjuverende behandling</b>			
TROPION-03	A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (Dato-DXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant systemic Therapy (TROPION-Breast03)	AKV/abd	09/23
Nordic Trip Trial	Nordic Trip/ NBG-1; a translational randomized phase III study exploring the effect of the addition of capecitabine to Carboplatinum based chemotherapy in early "triple negative" breast cancer	SY/lgs	12/22
DESTINY-05	A Phase 3, Multicenter, Randomized, Open-Label, Active-controllet Study of Trastuzumab Deruxtecan (TDXd) versus Trastuzumab Emtansine (T-DM1) in subjects with high-risk her2-positive primary breast cancer who have residual invasive disease in breast or axillary lymph nodes following neoadjuvant therapy (T-DXd vs. T-DM1 in high-risk HER2-positive patients with residual invasive breast cancer following neoadjuvant therapy)	SY/abd	01/22 (11/23)
<b>Recidivbehandling</b>			
REMERGE WO44977	A MULTI COHORT TRANSLATIONAL RESEARCH STUDY TO INVESTIGATE MECHANISMS OF RESISTANCE TO BREAST CANCER THERAPIES	TL/cb	06/24
CO44194	A Phase II, Multicenter, Randomized, Double-Blind Study of RO7247669 Combined with Nab-Paclitaxel Compared with Pembrolizumab Combined with Nab-Paclitaxel in Participants with Previously Untreated, Pd-L1-Positive, Locally-Advanced Unresectable or Metastatic Triple-Negative Breast Cancer	TL/cb	04/24
DESTINY-06	A Phase 3, Randomized, Multi-center, Open-label Study of Trastuzumab Deruxtecan (T-DXd) Versus Investigator's Choice Chemotherapy in HER2-low, Hormone Receptor Positive Breast Cancer Patients whose Disease has Progressed on Endocrine Therapy in the Metastatic Setting (DESTINY-Breast06)	AKV/abd	12/20 (01/23)
TNBC 355	Klinisk forsøg (fase III) der sammenligner behandling med pembrolizumab og kemoterapi med placebo og kemoterapi af tripel-negativ brystkræft	TL/la	09/16 (04/18)

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<b><u>Team 5</u></b>			
<b><u>Prostatacancer</u></b>			
PROstate PROTON Trial 1	(PRO-PROTON 1) Lymph node radiation therapy with integrated boost to prostate for high-risk prostate cancer A randomized phase 3 trial comparing photons vs. protons	JSØ/cb	08/23
PROstate Pilot	Lymph node radiation therapy with integrated boost to prostate for high-risk prostate cancer. A randomized phase 3 trial comparing photons vs. Protons	JSØ/cb	11/22 (06/23)
PRECANU	Frequency and classification of acute radiation-induced diarrhoea in patients with prostate and rectal cancer during curative external radiotherapy	JSØ/la+moh	05/22
PRIMORDIUM	A Randomized, Controlled, Multicenter, Open-label Study to Investigate the Efficacy and Safety of Adding Apalutamide to Radiotherapy and LHRH Agonist in High-Risk Patients with PSMA-PET-Positive Hormone-Sensitive Prostate Cancer, with an Observational Follow-up of PSMA-PET-Negative Patients	JSØ/cb	03/21 (03/24)
AMPLITUDE	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)	MMK/cb	03/21 (07/23)
Keynote 991	A phase 3, Randomized, Double-blind Trial of Pembrolizumab (MK-3475) Plus Enzalutamide Plus ADT Versus Placebo Plus Enzalutamide Plus ADT in Participants With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) (KEYNOTE-991)	MMK/lgs	05/20 (06/21)
CheckMate 650	A Phase 2 Trial of Nivolumab Plus Ipilimumab, Ipilimumab Alone, or Cabazitaxel in Men with Metastatic Castration-Resistant Prostate Cancer	MMK/la	10/19 (02/22)
SPCG-15	Kirurgi eller strålebehandling ved lokalt udbredt prostatakraft - et åbent lodtrækningsforsøg	MMK/fh	11/16
<b><u>Blærecancer</u></b>			
<b><u>Adjuverende</u></b>			
TOMBOLA	Treatment Of Metastatic Bladder cancer at the time Of biochemical reLApse following radical cystectomy	AC/lgs	11/20 (04/24)

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<b><u>Metastaserende</u></b>			
BO44157	A PHASE II, RANDOMIZED, MULTICENTER, OPEN-LABEL, CONTROLLED STUDY OF RO7247669 ALONE OR IN COMBINATION WITH TIRAGOLUMAB VERSUS ATEZOLIZUMAB IN PATIENTS WITH PREVIOUSLY UNTREATED LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER WHO ARE INELIGIBLE FOR PLATINUM-CONTAINING CHEMOTHERAPY	AC/lgs	07/23
BLADDER 100 rollover	AN OPEN-LABEL STUDY FOR CONTINUED TREATMENT ACCESS FOR PARTICIPANTS FROM THE B9991001 AVELUMAB STUDY	AC/la	12/22
EV302	An open-label, randomized, controlled phase 3 study of enfortumab vedotin in combination with pembrolizumab versus chemotherapy alone in previously untreated locally advanced or metastatic urothelial cancer	AC/cb	09/21 (10/22)
CheckMate 901	Et fase 3, åbent, randomiseret studie med Nivolumab kombineret med enten Ipilimumab eller standard kemoterapi versus standard beh. Med kemoterapi til pt. med tidligere ubehandlet lokal avanceret inoperable eller metastatisk urotelialt karcinom	AC/la	06/18 (09/22)

Protokolregi/nummer	Kort titel/beskrivelse	Investigator/ projektsygeplejerske	Aktiveret/ (lukket)
<b><u>Team 6</u></b>			
<b><u>Hoved-halscancer</u></b>			
Spørgeskemaundersøgelse	Influence of socioeconomic, psychosocial and geographical factors on participation in clinical proton radiotherapy trials among Danish patients with head and neck cancer	MA/lr	08/22
DAHANCA 37	A phase II study of intensity modulated proton therapy (IMPT) for re-irradiation with curative intent for recurrent or new primary head and neck cancer	MA/ljs	06/20
DAHANCA 35	Et lodtrækningsforsøg mellem proton strålebehandling versus røntgen strålebehandling af hoved-hals kræft	MA/ljs	06/19
DAHANCA 33	Dosis-eskaleret strålebehandling vejledt af funktionel billeddannelse til patienter med hypoksisk hoved-halscarcinom	MA/ljs	06/18
DAHANCA 30	Et randomiseret non-inferiority studie af hypoxi-profilvejledt nimorazolbehandling i forbindelse med primær strålebehandling af planocellulære hoved-halscarcinomer	MA/ljs	01/17
<b><u>Personlig medicin</u></b>			
ProTarget	A Danish Nationwide Clinical Trial on Targeted Cancer Treatment based on Genomic Profiling	ML/la	01/22
ProSeq Cancer	En prospektiv undersøgelse af omfattende genomiske analyser hos patienter med uhelbredelig kræft, med henblik på målrettet behandling	ML/lgs	07/20
<b><u>Stereotaksi</u></b>			
<b><u>Tværgående</u></b>			
ImmunoCase	Vurdering af respons efter immunterapi i Lynch syndrom-associeret kræft Retrospektiv undersøgelse af immunologiske biomarkører — herunder undvigelse af immunforsvaret — med henblik på at kunne prædikere behandlingsrespons	ML/cbn	04/24
CSI ProLong	Phase II study of Proton Cranio-spinal irradiation for leptomeningeal metastasis	WS/mer	02/24