PHASE 1 AND FIH ONCOLOGY/HEMATOLOGY UNITS IN SWEDEN

Last update: 2025-04-11

SWEDEN, WORLD-CLASS EARLY PHASE CLINICAL TRIAL COUNTRY

- Sweden is an innovation leader in Europe, with highly attractive research systems, among countries with the highest number of international scientific co-publications and most cited / highly cited publications and having a high percentage of doctorate graduates in the healthcare sector.
- Sweden's four academic-based early phase clinical units are located in large academic comprehensive cancer centers (certified or under certification) renowned for performing high- impact cutting-edge scientific research, as shown by OECI/CCs evaluations.
- Early phase staff works closely with state-of-the-art pathology and precision medicine centers to allow fast and optimal patient match and, all early phase units collaborate with leading clinician-investigators specializing in a variety of tumor types.
- State of the art nuclear imaging for determination of drug distribution, receptor occupancy and drug pharmacodynamics.
- ATMP centers with JACIE accreditation.
- This unique ecosystem allows collaboration among the early phase network and other national and international networks and initiatives to ensure adequate patient recruitment.

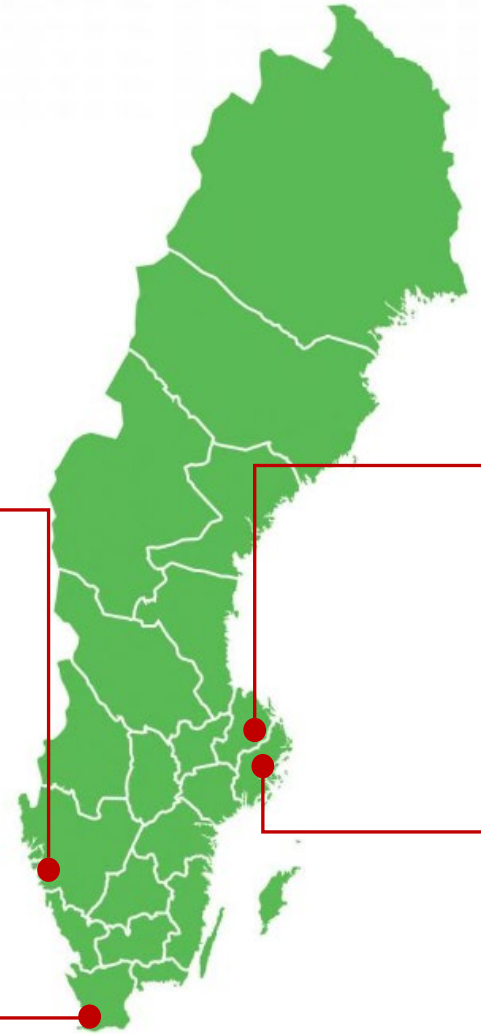
SWEDEN'S FOUR EARLY PHASE CLINICAL UNITS IN CANCER

- COVER ALL PARTS OF SWEDEN
- 10.5 MILLION INHABITANTS

National network between the University Hospitals

NASTRO

Nätverket för Universitetssjukhusens Prövningsenheter inom Onkologi



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Karolinska Comprehensive Cancer Center

WHY CHOOSE SWEDEN?

Collaborations

Collaboration within national network NASTRO and a database for ongoing oncology and hematology trials at all hospitals

National registers and National patient overview, no lost to follow-up

Nordic Molecular Tumor Board and possibility to include international patients

National collaboration with pre-clinical experts from SciLifeLab

Availability

The insurance system guarantees all citizens advanced medical care. This setup ensures that a diverse patient population is included in clinical trials, representing all parts of the Swedish society

Patients are discussed at multidisciplinary conferences to identify possible treatment and available clinical trials

Efficacy

Quick data entry and high data quality since study coordinator enter data and respond to queries (not data managers)

Sweden is a cost-effective country for conducting studies. Hospitals charge for actual costs according to Swedish regulations

Overarching CDAs covering all study discussions with governmental hospitals

High level English proficiency. Translation of Cover Letter or CTIS data fields is not needed

Secured structure for local sourcing of IMP

Low drop out rate. Patients in Sweden exhibit a strong commitment and adherence to rules

High digital maturity in the whole population

Regulatory

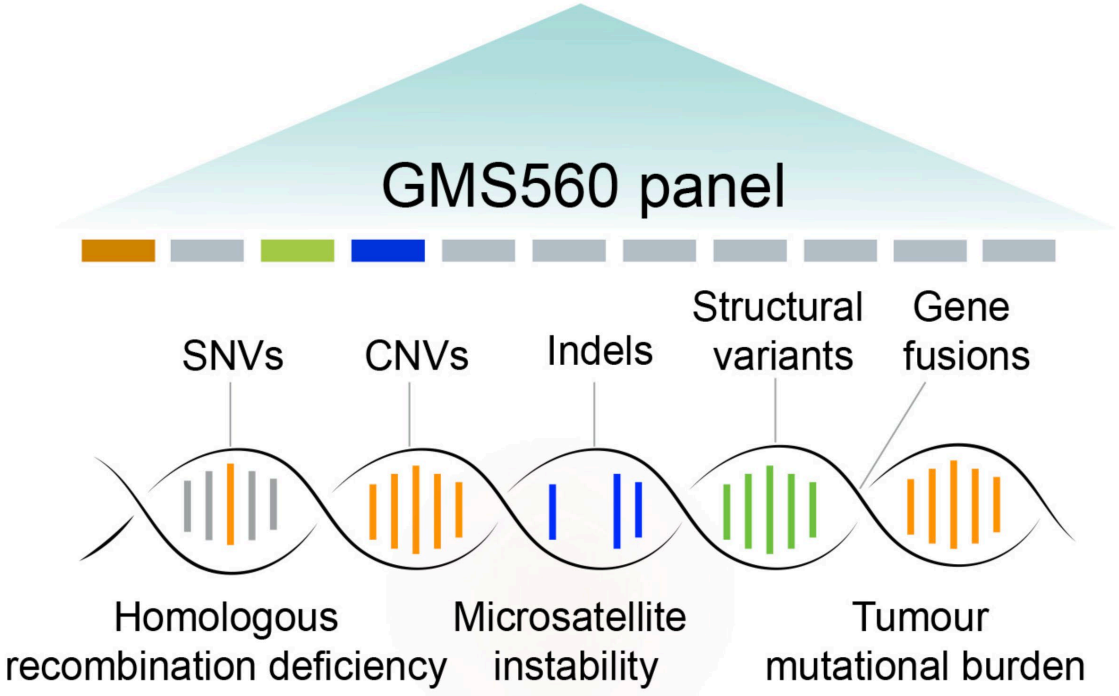
Strong commitment and adherence to regulations and agreements

Regular inspections from Swedish MPA to assure that routines and facilities maintain high quality

BROAD MOLECULAR PROFILING AND VARIANT CALLING; MOLECULAR TUMOR BOARD FOR PATIENTS WITH ADVANCED CANCER

ESTABLISHED IN ALL CENTRA

Genomic pipeline: from tumor analysis to treatment decision



Solid tumours | Genomic Medicine Sweden

Hematology | Genomic Medicine Sweden

DESCRIPTION OF THE SWEDISH PHASE I UNITS

Specification	Karolinska	Sahlgrenska	Skåne	Uppsala
Comprehensive Cancer Center since year (OECI)	2020	2022	2022	Planned May 2025
Disease areas of main interest/expertise	All solid tumors All hematology Non cancer and healthy volunteers	All solid tumors All hematology	All solids All hematology	All solids All hematology Non cancer
Inhouse research council	Weekly	Biweekly	Biweekly	Biweekly
Conducted FiH trials since year	2002	2023	2018	2000
Number of treatment beds	17 beds for FiH. 60 additional beds for other phase I and later phases	2 dedicated beds for FIH-phase I in lead-lined room. 45 beds available for other phase I	3 dedicated inward beds for early phase trials	3 dedicated beds for FiH. 50 beds for other phase I and later phases
Latest inspection by Competent Authority (CA); Medical Product Agency (MPA) every 3rd year for FiH pre-approval	Jan 2025 (pre-approval since 2012)	Planned April 2025	TBD	Nov 2023
Available imaging	CT, MRI, PET-CT, PET-MRI, SPECT-CT, Bone Scan, ECHO	CT, MRI, PET-CT, PET-MRI, Bone Scan, ECHO/MUGA	On-site: CT, MRI, PET-CT, PET-MRI, Bone Scan, ECHO/MUGA Oncology dedicated: CT-scans/MRI	CT, MRI, PET-CT, PET-MRI, Bone Scan, ECHO/MUGA MR-Linac

DESCRIPTION OF THE SWEDISH PHASE I UNITS

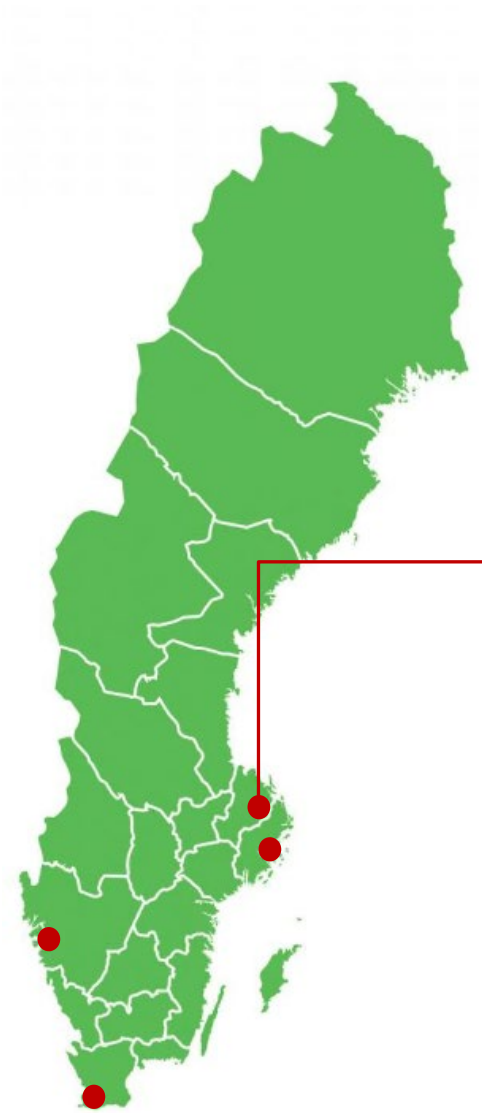
In addition, all Units have:

- Resources available 24/7 on call
- On site emergency room (ER) and intensive care unit (ICU)
- Availability to perform paired biopsies
- Time from request of biological sample to actual shipment of samples within or outside EU takes 2-3 days
- All equipment certified and controlled; Temperature logs for all refrigerator and freezers; Dedicated equipment for early Phase with controlled access
- MSA (Master Service Agreements) and WO (Work Orders) or Clinical Trial Agreements
- Site contracts as well as Biobank application will be done in parallel with the CTIS application
- Internal processes for contracting Lab/MRI/Eye clinic etc, costs will be included in the site contracts
- Separate Pharmacy Agreements needed
- High recruitment reliability for available slots. Internal follow-up

- For more details see Unit specific slide decks

UNIT SPECIFIC SLIDES

Uppsala University Hospital



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PHASE I UNITS UPPSALA (SWEDEN)

Uppsala University Hospital

KFUE Phase I Unit, Dept. of Oncology, Haematology and Endocrine tumours

KFUE Phase I Unit

TABLE OF CONTENT

- Introduction
- Team
- Description of the Unit
- Phase I studies performed, and patients included
- Area of expertise

INTRODUCTION

Name of the Phase I Unit:

- KFUE Phase I Unit

Name of Hospital:

- Uppsala University Hospital

Brief history:

- Within Uppsala University Hospital, unique knowledge and the most advanced care is available. Every year more than 700 000 patient seek care at our hospital.
- FIH (First in Human) and Phase I studies have been conducted since **2000** within the Dept. of Oncology, Hematology and Endocrine Tumors. The Phase I Unit is today self-funding and has extensive experience in endocrine tumours and immunological trials as well as hematological and **CAR-T** trials, with **JACIE** accreditation for stem-cell transplants and CAR-T.
- Currently approximately 170 cancer trials are being conducted at KFUE in different phases. 18 are Phase I studies of which 5 is FIH.
- The department receives referrals from all of mid-Sweden with a population of 2.1 million inhabitants via regular regional Multi-diciplinary conferences. In Phase I studies patients are recruited from all of Sweden.

TEAM

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Head of Department

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Medical Director for KFUE and Phase I

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Mattias Mattsson

Medical Director KFUE Hematology

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AKADEMISKA SJUKHUSET

WHY RUN A STUDY AT UPPSALA UNIVERSITY HOSPITAL!

- Uppsala University Hospital is a Centre of Excellence for Endocrine Tumors and is today one of the world leading centers for diagnosis and treatment for neuroendocrine tumors (NET's).Yearly 100 patients from the whole world is referred to the hospital
- Other areas where **national** referrals to the hospital occur; HIPEC, anal cancer, and adrenal malignancies, and head- and neck paragangliomas
- Collaboration with PET center for diagnosis with Pet Tracers and therapy as for ex Peptide radio receptor therapy (PRRT) is well established
- Extended experience with CAR-T trials since 2014.
- Groundbreaking preclinical research across the field of molecular biology, cancer genetics and immunotherapy
- Translation of preclinical research to clinical trials through close collaboration between basic and clinical scientists
- Nationally and internationally highly ranked research infrastructures
- A well-developed unit for conducting academic as well as company supported clinical trials phase I-III

AKADEMISKA SJUKHUSET

DESCRIPTION OF THE UNIT

- The Unit has 10 experienced Phase I Investigators, and 2 Medical Leads.
- Four Principal Investigators work within Hematology and 6 with Solid Tumors, all with experience from both early phase clinical trials and specific diagnose competence.
- The Unit has 18 nurses/coordinators, of which 6 are dedicated to the Phase I Unit. In addition, the Unit has 2 assistant nurses.
- The hospital has their own Pharmacy department with great clinical trial expertise. Also possible to use other Pharmacy if required

- The Unit's primary methods of recruitment is via referrals, often after case presentations at regional and national Multi-Diciplinary Conferences, and collaborations within mid-Sweden.
- To increase patient retention decentralized trials (DCT)/components can be utilized in the Unit. The department works with "satellite sites" in mid-Sweden and has the possibility to perform video calls with patients. Digital solution for consent feasible. Open to using other digital solutions.

AKADEMISKA SJUKHUSET

NUMBER PHASE I STUDIES ONGOING

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase I (excl. FIH)	12	18	18	16	16	10
First In Human (FIH)	4	5	5	4	4	3

NUMBER OF PATIENTS INCLUDED

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase I (excl. FIH)	17	23	31	36	30	27
First In Human (FIH)	2	10	14	5	16	5

AKADEMISKA SJUKHUSET

AREA OF EXPERTISE (UNIT)

- What specific methods can be performed at your unit?
  - Collaboration with SciLifeLab Uppsala with an extensive range of sampling capabilities
  - Collaboration with Genomic Medicine Sweden
  - Close collaboration with Uppsala Precision Medicine Center and ATMP-center
  - We have the knowledge and resources to perform all different types of clinical research within oncology and hematology
- Experience with Advanced Therapy Medicinal Products (ATMP) studies, CAR T, viruses and T-cells etc.
- Diagnose specific biomarker tests are done by default on newly diagnosed patients, and;
  - NGS is widely used and the GMS560 panel is implemented in clinical routine for solid tumors
  - Gene panel from GMS for myeloid malignances is clinical routine
  - Ongoing pilot project since several years for broad characterisation of lung, breast and ovarial cancers and full genomic sequencing of leukemia
  - Timelines to response 3-4 weeks in clinical routine

AKADEMISKA SJUKHUSET

BIOMARKERS

- **DONE BY DEFAULT ON NEWLY DIAGNOSED PATIENTS**

GI

S/CEA
S/CA19-9 (pancreas)
MMR (all)
NGS-panel to examine mutations in KRAS, NRAS, BRAF (CRC)
CPS-score (ventricle/esofagus)
Her-2 (ventricle)
NTRK (all)

Endocrine

BRAF
gene sequencing
NGS (GMS560)
MEN-1 panel

URO

Prostate: PSA, BRCAI/BRCA2
Blatter: Lynch syndrom, PDL1

GYN

S/CA 125
sometimes S/BRCAI/BRCA2
Corpus cancer: GMS560 in 2-3 months, immunhistochemistry for MMR proteins (and sometimes also PCR), immunhistochmistry p-53, immunhistochemistry ER and Pr.
Cervix cancer: PD-L1 with immunhistochemistry according to CPS (combined positive score)
Ovarial cancer: HRD-analysis, BRCA1/BRCA2

Lymphoma

GMS560

Lung

NGS-panel (Illumna): EGFR, NRAS, KRAS, BRAF, PIK3CA, HER2, MET.
Transcriptional analysis, (NanoString):ALK, ROS1, RET, exon 14.

Breast

S-CA-15-3, ER, PR, HER2, BRCA, PIK3CA, ESR1, PDL1.
PAM50-genexpression analysis in certain cases.
NGS (Next Generation Sequencing) will be introduced in a forseable future

Melanoma

High-risk and generalized condition: BRAF
Advanced illness: PDL1

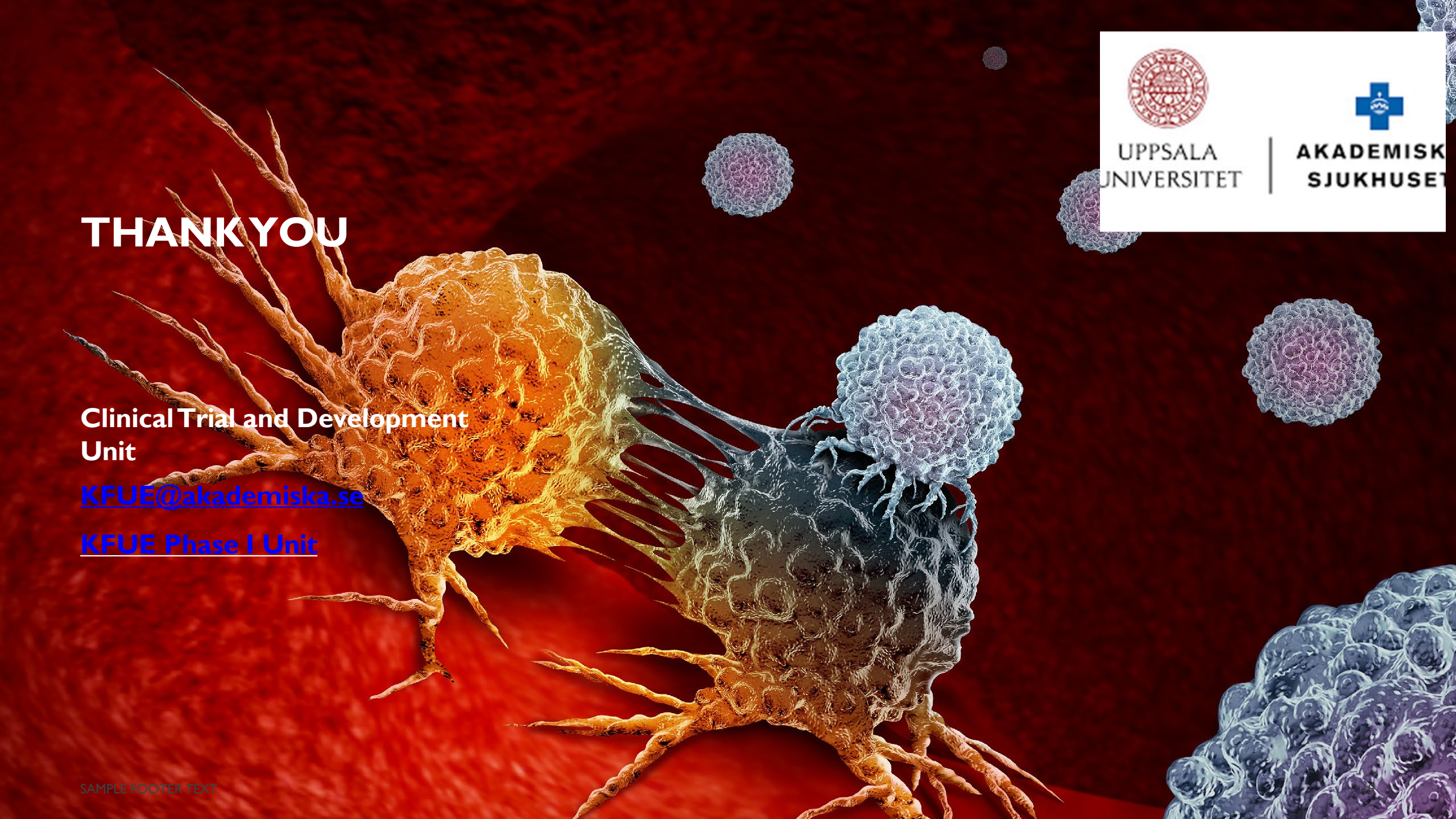
HoN

AREA OF EXPERTISE (PHYSICIANS)

- Connection with academic institution(s)/ networks/Life Science start-up and/or industry?
  - German Hodgkin Study Group
  - Nordic Lymphoma Group
  - Stichting European Myeloma Network
  - Hovon, Kancera
  - Lokon Pharma AB
  - BioInvent
  - Alligator Biosience
  - Elicera Therapeutics AB
  - Universities: University of Cologne, Aarhus University, Oslo University hospital and all major Swedish University hospitals

- Disease areas of main interest/expertise
  - Solid tumours including immunoncology, CAR-T,
  - Haematology
  - Endocrinological oncology, including PRRT
  - All novel therapies

AKADEMISKA SJUKHUSET



THANK YOU

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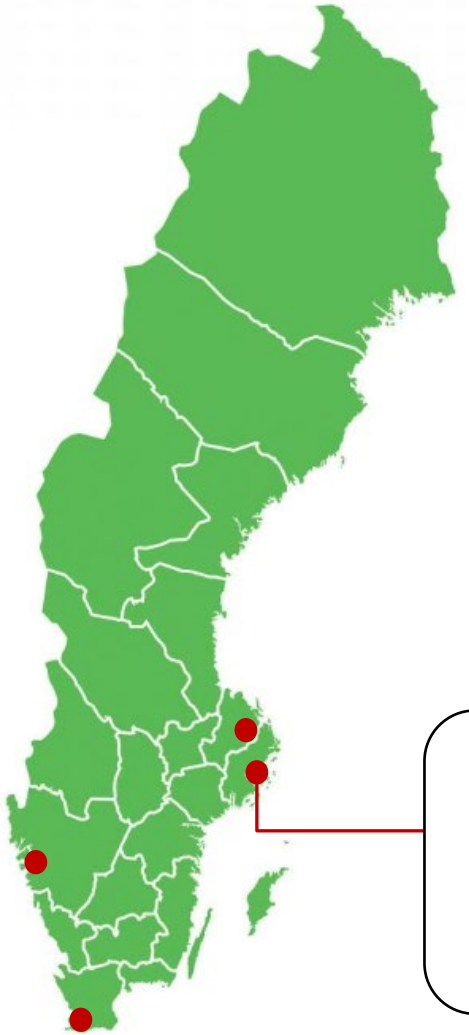
KFUE Phase I Unit

UNIT SPECIFIC SLIDES

Karolinska University Hospital



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PHASE 1 UNITS STOCKHOLM (SWEDEN)

Department of Clinical Cancer Studies

Karolinska Institutet | KAROLINSKA UNIVERSITY HOSPITAL

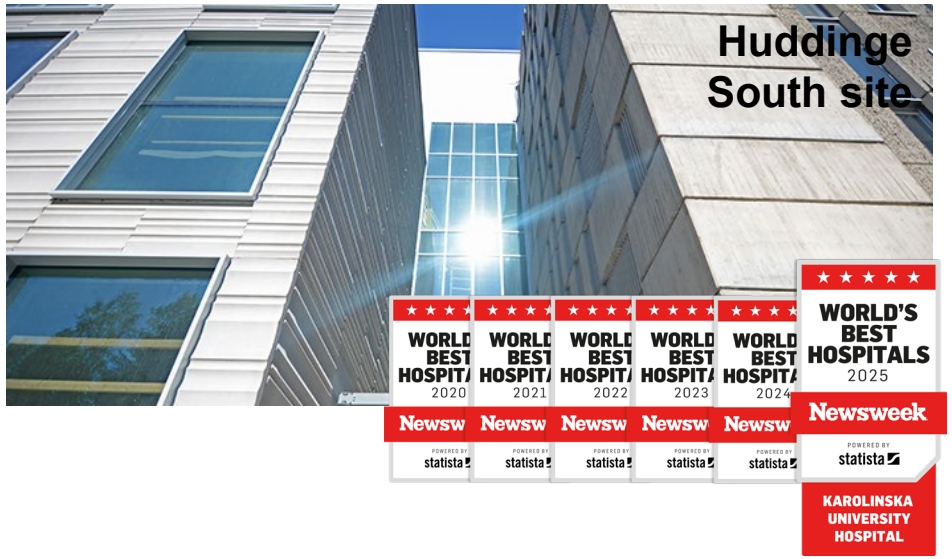
Karolinska Comprehensive Cancer Center

TABLE OF CONTENT

INTRODUCTION

Karolinska Comprehensive Cancer Center

- Karolinska University Hospital
- Department of Clinical Cancer Studies
  - Phase 1 Unit Solna
  - Phase 1 Unit/Cancer Study Unit Huddinge
- Brief history:
  - Ranked as one of World´s Best Specialized Hospitals
  - One hospital at two sites with over 16 000 employees
  - Stockholm has over 2 million inhabitants
  - Highly specialized care for national and international patients
  - A strong collaboration with Karolinska Institutet and SciLifeLab
  - State of the art nuclear imaging for determination of drug distribution, receptor occupancy and drug pharmacodynamics
  - Over 400 ongoing clinical studies for cancer patients in different phases within oncology and hematology
  - Over 40 ongoing Phase 1 cancer trials
  - Dedicated unit for early oncology trials since 2010
  - Molecular Tumor Board run through the Phase 1 Unit since 2021



LEAD
PHASE 1 UNITS

- Caroline Brav

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Solid tumors and lymphoma or combined trials for solid tumors and hematology
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- Sofie Sibia

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- Luigi De Petris

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- Maria Creignou

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THE TEAM

- 22 highly-skilled investigators
  - 6 dedicated Phase 1 investigators working in the Phase 1 Units with internationally recognized expertise in oncology and hematology
  - 16 additional experienced investigators with Phase 1 competence within oncology and hematology available at site
- 16 experienced study nurses / study coordinators dedicated for early clinical trials
- 7 blood and tissue sampling coordinators

PATIENT RECRUITMENT

- Units' primary methods of recruitment;
  - Inhouse referrals, national and international referrals
- Around 20 referrals per week to Phase 1
  - 40% external
- Digital health solutions
  - Ongoing implementation of e-consent
  - Patient video calls available for secure online physician consultations

NUMBER OF ONGOING PHASE 1 CANCER TRIALS

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase 1 (excl. FIH)	26	39	37	30	25	20
First In Human (FIH)	14	18	14	10	7	6

NUMBER OF PATIENTS INCLUDED IN CANCER TRIALS

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase 1 (excl. FIH)	22	45	23	34	25	21
First In Human (FIH)	24	40	29	25	21	22

MOLECULAR TUMOR BOARDS

- Well-established National, Nordic and European clinical collaborations for genomic-based treatment recommendation and clinical trial inclusion
  - Bi-weekly local Molecular Tumor Board
  - Monthly Nordic Molecular Tumor Board
  - Weekly European Molecular Tumor Board with Cancer Core Europe (CCE) and CCE Phase 1 team
  - Karolinska International Patient Office (IPO) for cross-border patients with rare diseases or mutations

ROUTINE MOLECULAR TESTING AVAILABLE AT KAROLINSKA

Tumor Type	IHC	MOL
Lung	PD-L1	Oncomine Focus DNA/RNA
CNS		Oncomine Childhood
CUP		Oncomine Childhood, pilot project with whole genome sequencing (WGS) 2025
Colorectal	MSI/dMMR; HER2	Oncomine Solid DNA
Upper GI	MSI/dMMR; HER2; PD-L1; NTRK 1-3	Oncomine Solid DNA
Gyn	HRD	BRCA1/2, NGS for endometrial cancer 2025
Pediatric		WGS
Breast	ER, PgR, HER2, PD-L1	BRCA1/2, NGS in metastatic disease during 2025/2026
Sarcoma		WGS
Uro	PD-L1 (Bladder)	BRCA1/2 (Prostate)
H&N	PD-L1, HPV	
Melanoma	PD-L1	BRAFV600E
Myeloid malignancies (AML, MDS, MPN)		Cytogenetic RT-PCR *RUNX1*:*RUNX1T1*, *CBFB*:*MYH11*, *PML*:*RARA* In-house panel sequencing (~160 genes). WGS in AML/ALL 2025
Lymphoid malignancies	FISH BCL-2/ BCL-6 och C-MYC	GMS lymphoid panel in young patients and T-cell lymphoma
Plasma cell neoplasia		*t(4;14), t(11;14), t(14;16), del(17p), del(1p) och dup(1q21) on CD138 sorted cells.*

In-house broad NGS screening panel for phase 1 eligible candidates and within Cancer Core Europe screening program

COMPETENCE AND CAPABILITIES

- Experience across a broad range of early clinical trials
  - Diverse FiH, phase 0, ATMP, GMO
  - Dedicated Phase 1 Team with nationally/internationally recognised expertise
  - Integrated Hematology and Oncology within the same department
- Advisory capabilities for biotech and small pharmaceutical companies
- Official price lists at [Forskningsprislistor (karolinska.se)]

CONNECTION WITH ACADEMIC INSTITUTIONS/ NETWORKS/LIFE SCIENCE START-UP AND/OR INDUSTRY

- Karolinska Institutet (KI)
- Karolinska Comprehensive Cancer Center
  - Accredited 2020, a joint venture between the hospital and Karolinska Institutet (KI)
- Cancer Core Europe member
  - A network of 7 leading European cancer centers: NKI, Gustave Roussy, VHIO, Heidelberg, Cambridge, INT Milano, KI
  - Molecular Tumor Board
  - Ongoing basket trial
  - Phase 1 collaboration
- Nordic MTB
  - A Nordic Molecular Tumor Board consisting of personnel from phase I units in Denmark, Finland, Norway and Sweden, performing early clinical trials in oncology
- SciLifeLab
  - State-of-the-art innovative multiomics and gene sequencing technology
- Karolinska ATMP-center
  - JACIE accredited, CAR-T, TCR, adoptive T-cell therapy, GMP-production
- Theranostic Trial Center Karolinska (TTCK)
  - Radiopharmacy; PET-tracers and PET/radio-ligands, receptor occupancy, GMP-production
- PET-Center KI
- Collaboration with biotech industry
  - In preclinical studies within the framework of the Phase 1 Unit
  - In an advisory capacity helping with study design

THE PHASE 1 INVESTIGATORS PARTICULAR AREA OF EXPERTISE

- Jeffrey Yachnin; Uro- and Breast cancer
- Luigi de Petris; Lung cancer
- Maria Creignou; Hematology (including lymphoid malignancies)
- Maximilian Kordes; GI-cancer
- Oscar Wiklander; Breast cancer
- Lisa Liu Burström; Uro- and GI-cancer

DEPARTMENT OF CLINICAL CANCER STUDIES

- Phase 1 Unit Solna
- Phase 1 Unit/Cancer Study Unit Huddinge

Karolinska Institutet | KAROLINSKA UNIVERSITY HOSPITAL

Karolinska Comprehensive Cancer Center

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CLINICAL TRIAL UNIT CTU, DEPARTMENT OF ONCOLOGY, SAHLGRENSKA UNIVERSITY HOSPITAL

Sahlgrenska Comprehensive Cancer Centre

UNIVERSITY OF GOTHENBURG Sahlgrenska Academy

REGION VÄSTRA GÖTALAND SAHLGRENSKA UNIVERSITY HOSPITAL

TABLE OF CONTENT

- Introduction
- Team
- Description of the Unit
- Phase I studies performed, and patients included
- Area of expertise

INTRODUCTION

Name of the Phase I Unit:

- *Clinical Trial Unit CTU, Department of Oncology*

Name of Hospital:

- *Sahlgrenska University Hospital*

Brief history:

- *As the largest hospital in Sweden (17.700 imployees) it offers best care and conducts world-class research, development, education and innovation for the benefit of patients. The hospital has internationally outstanding treatment offerings and has an accreditation as Comprehensive Cancer Center (CCC) since 2022.*

- *1.7 million people are living in the area that can be referred to the hospital. In clinical trials subjects from all over Sweden can be included. Currently about 215 clinical trials in different phases within oncology. Hematology and surgery are performed. Strong Collaboration with Pediatric Clinical Trial Unit*
- *FIH (First in Human) and Phase I studies have been conducted since 2010 within the Department of Oncology.The Phase I Unit is self-funding and has extensive experience in early clinical trials*

TEAM

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Sahlgrenska Academy

REGION VÄSTRA GÖTALAND
SAHLGRENSKA UNIVERSITY HOSPITAL

CLINICAL TRIAL UNIT CTU, OUR STRENGTHS

Sahlgrenska University Hospital is the first Nordic hospital to be certified Breast Cancer Center by EUSOMA

First Nordic center with ATMP within pediatric cancer

Assigned National specialized medical caregivers in several diagnosis. The Unit's primary methods of recruitment are own patients and referrals from colleagues in Scandinavia

Groundbreaking preclinical research across the field of molecular biology, cancer genetics and immunotherapy

Translation of preclinical research to clinical trials through close collaboration between basic and clinical scientists

Nationally and internationally highly ranked research infrastructures

Two well-developed units for conducting academic as well as company supported clinical trials phase I-II

DESCRIPTION OF THE UNIT (1/2)

The Unit has 9 experienced Phase I Investigators within hematology and solid tumours and a Medical Lead Director.

The Unit has 16 research nurses/coordinators, of which 4 are dedicated to the Phase I Unit. In addition, the Unit has 2 assistant nurses.

Resources available for 24/7 on call.

Specificbeds in lead-lined room are available for FIH studies

50 treatment beds available for clinical trials at the department of oncology. On site Emergency Room (ER) and Intensive Care Unit (ICU).

The Unit's primary methods of recruitment is via referrals, often after case presentations at regional and national Multi-Diciplinary Conferences, and national collaborations.

Digital solution for consent feasible. Open to using other digital solutions.

NUMBER PHASE I STUDIES PERFORMED (ONCOLOGY)

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase I (excl. FIH)	3	9	6	2	2	0
First In Human (FIH)	0	0	1	1	0	0

NUMBER OF PATIENTS INCLUDED (ONCOLOGY)

Type of Study	Year 2024	Year 2023	Year 2022	Year 2021	Year 2020	Year 2019
Phase I (excl. FIH)	6	12	18	11	8	0
First In Human (FIH)	0	0	2	7	0	0

HEMATOLOGY: 2 ONGOING TRIALS 2024

AREA OF EXPERTISE

- What specific methods can be performed at your unit?
  - Collaboration with Sahlgrenska Center for cancer research with an extensive range of sampling capabilities and analyses.
  - Collaboration with Sahlgrenska Life
  - Collaboration with Genomic Medicine Sweden
  - Close collaboration with Sahlgrenska Precision Medicine Center and ATMP-center
  - Knowledge and resources to perform all different types of clinical research within oncology and hematology

- Diagnose specific biomarker tests are done by default on newly diagnosed patients, and;
  - GMS560 panel is available in clinical routine and for trials
  - NGS characterisation of lung, breast and ovarial cancers in clinical routine.
  - Timelines to response 3-4 weeks in clinical routine

- Experience with Advanced Therapy Medicinal Products (ATMP) studies, CAR T, vaccines and T-cells
- Strong research and collaborations in Immunotherapy and Radionuclide therapy

BIOMARKERS

GI:
MSIH, S/CEA, MMR, NTRK

Ventrikel:
HER2, EBV, CPS-score, NTRK

Colorektal:
NGS-panel to examine mutations in KRAS, NRAS, BRAFV600E, MSI

Pancreas:
S/CA19-9

Esophagus:
CPS, HER2, NTRK

Prostata:
PSA

Lung:
NSCLC:
NGS-panel to examine mutations in EGFR, ALK, ROSI, BRAF, RET, Met exon 14 skipping, NTRK

Headneck:
PDL1 CPS

Corpuscancer:
MSIH

Ovarial:
BRCA/HRD, GMS560 is under implementation

Cervix:
PD-L1-analys with CPS

Neuroendocrine:
BRAF, gene sequencing NGS (GMS560), MEN-1 panel, Chromogranin A

Glioma: MGMT, Fish, DNA and RNA mutation analysis

Breast:
oncocyte test, + genpanel BRCA, S-CA-15-3, ER, PR, HER2, PIK3CA, ESR1, PDL1. PAM50-genexpression analysis in certain cases. NGS is under implementation

Lymphoma:
FACS, Immunohistochemistry, FISH, NGS, IGH/TCR

Melanoma:
BRAFV600 (if negative: BRAFV600X, NRAS, NF1 and C-kit with panel), PDL1

THANK YOU!

annika.baan@vgregion.se

edvard.abel@vgregion.se

kajsa.holgersson@vgregion.se

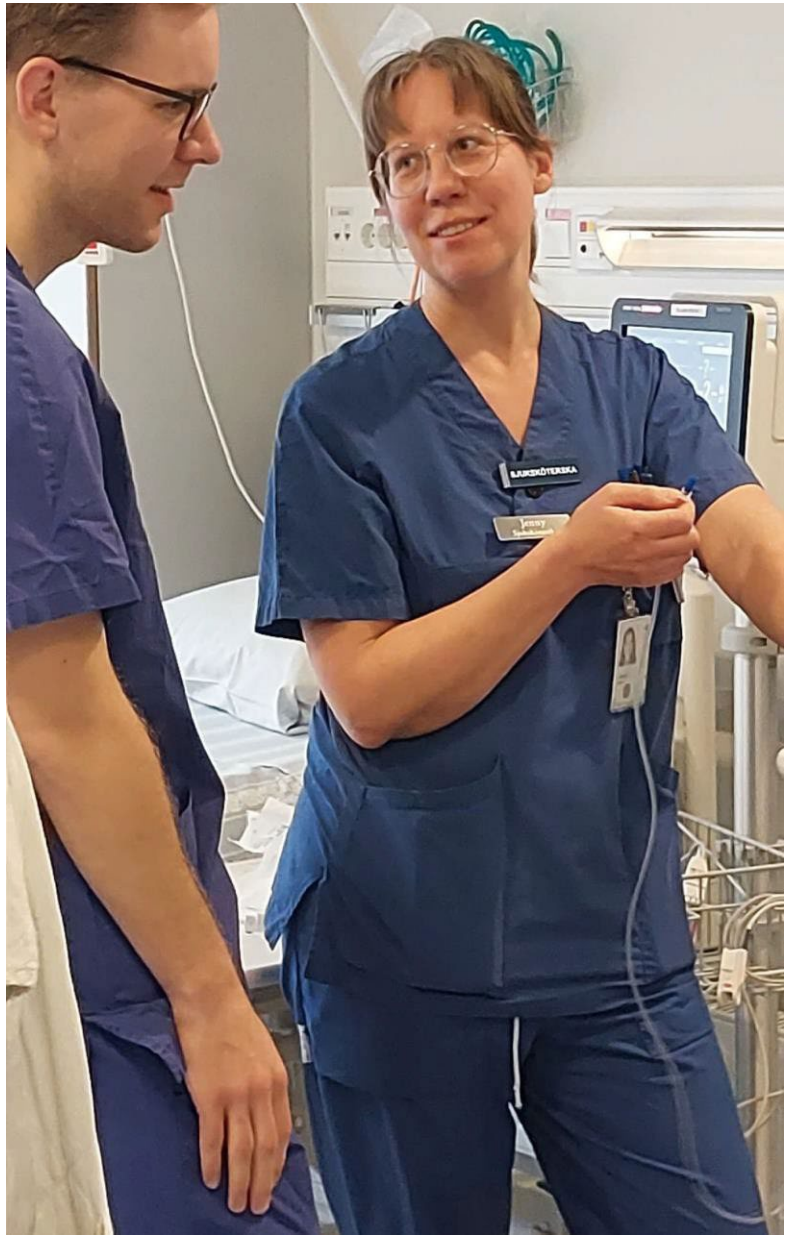
Website

Klinisk prövningsenhet FAS 1/FIH - Sahlgrenska Universitetssjukhuset

Sahlgrenska Comprehensive Cancer Centre

Sahlgrenska Academy

REGION VÄSTRA GÖTALAND SAHLGRENSKA UNIVERSITY HOSPITAL



UNIT SPECIFIC SLIDES

Skåne University Hospital

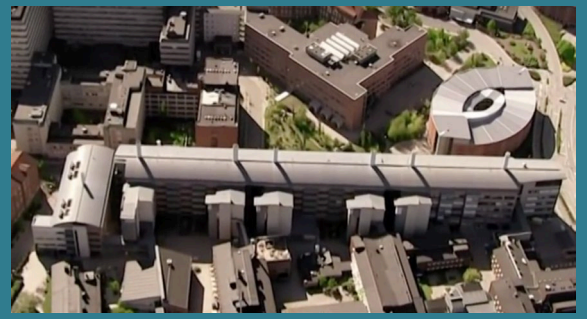
Skåne University Hospital
Phase 1 Unit
Klinforsk.onkologi.sus@skane.se
Johan.l.olsson@skane.se
Ana.caneiro@med.lu.se

EARLY PHASE CLINICAL TRIALS UNIT

DIVISION **HEMATOLOGY**, **ONCOLOGY**, RADIATION PHYSICS

SKÅNE UNIVERSITY HOSPITAL COMPREHENSIVE CANCER CENTER

LUND, SWEDEN

EARLY PHASE - LEAD TEAM

Head Early Phase
Johan Olsson
(Research Nurse)

Medical Director
Ana Carneiro
(MD, PhD, Associate Professor)

SKÅNE UNIVERSITY HOSPITAL COMPREHENSIVE CANCER CENTER

Comprehensive Cancer Centre (OECI)

ATMP Centre GMP facility (MPA)

Pathology Precision Medicine Centre

National Infrastructure for Biobanking

LUND UNIVERSITY & LUND UNIVERSITY CANCER CENTRE

Top 100 universities (various rankings)

Dedicated cancer research environment (LUCC)

Strong national & international collaborations

Ground-breaking pre-clinical research in life sciences

STRONG TRANSLATIONAL RESEARCH

Strong collaborations with clinicians

Highly innovative research: 60 spin-outs companies

Medicon Village: Industry & Academic collaboration

2,800 individuals, 180 companies

LUND UNIVERSITY

LUCC CANCER CENTRE

REGION SKÅNE

DIVISION HEMATOLOGY, ONCOLOGY, RADIATION PHYSICS

CAPTURE AREA

3 M (South)

TREATMENT AREAS

ALL

NEW PATIENTS/YEAR

7,000

REFERENCE CENTRE

For other geographical areas

REFERRALS

All Swedish Hospitals

FOREIGN REFERRALS

Possible (Sponsor)

EARLY PHASE CLINICAL TRIALS UNIT, LUND - SWEDEN

EXPERTISE

FIH and Phase 1
Dedicated staff

EXPERIENCED

Clinical Research Team

REGULATORY COMPLIANCE

SOPs
CTIS and Biobank submission

FACILITIES

Dedicated beds in JACIE ward
Direct ICU access
Own CT/MRI machines
Dedicated refrigerator/freezer

TRACEABILITY

Robust chain of custody of all samples (dedicated lab)

DEDICATED PHARMACY

Dedicated pharmacy team for IMP handling

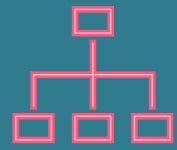
EARLY PHASE TEAM

Dedicated early trial team - hematology and oncology

4
Dedicated Phase 1 nurses

2
Dedicated physicians/trialists

Partnered with leading physicians across specialties for expert support in every diagnosis.



Supported by an experienced CTU

34 nurses
2 administratives
2 assistant nurses
3 laboratory scientists

OUR PRIORITY - PATIENT SAFETY FIRST

PATIENT SAFETY

- 24/7 early phase in patient care
- 24/7 crash team support / emergency response team support
- 24/7 oncology / haematology on-call & consultant services
- Oncology acute outpatient clinic

SAFETY MONITORING

- Solid processes for safety monitoring
- Electronic Journal System – access to any healthcare
- No data loss, 100% post-study safety follow-up
- No patient drop-outs

OUR COMMITMENT - SUCCESS OF EVERY TRIAL

EFFICIENT ENROLLEMENT

- 100% target enrollement
- Timely First Patient In

QUALITY OF DATA

- Accurate data
- Real-time data collection (data capture within 24 hours dosing)
- Low query volume & prompt query resolution
- Adherence to trial timelines

TRIAL ENGAGEMENT

- Close collaboration with sponsor
- 100% attendance safety meetings

EARLY PHASE WORKFLOW

- Singel Point of Contact (all feasibilities)
- Start-up team
- Limited internal committees
- Support during CTIS application
- Support during local contract negotiation and start-up
- **Parallell** negotiation of contract (during CTIS evaluation)
- 100 Days Goal (from Protocol Receipt Completion to site- activation)

WORKING FLOW - FAST TRACK

ONE POINT OF CONTACT

For all early-phase feasibilities and start-up work

Feasibility	Scientific Committee Evaluation	Clinical Trial Office	Coordinating Nurse
7 working days	Meets every 2 weeks	Start-up in parallel with CTIS submission	SIV as soon as CTIS approved

ALIGNED RESPONSABILITY AND AUTHORITY

- Dedicated staff with full Phase 1 focus
- Weekly protocol review meetings (PI and coordinators)
- Weekly follow-up of accrual, toxicity, responses etc
- Regular grand rounds (clinic) to discuss new protocols
- Regular communication between Early Phase and chairs/Lead Physicians
- Molecular reflex testing as per national guidelines (GMS560 on demand)

OUR EXPERTISE

IMMUNOTHERAPIES

- Monoclonal antibodies, bi- and trispecific, anibody fragments
- T-cell engagers (& antibody fragments)
- Intratumoral treatments (oncolityc virus therapy)

ATMP

- Cell therapy, CAR-Ts (first patient in Sweden)
- Gene therapy
- Vaccines (mRNA)
- Intratumoral treatment (virus)

SMALL MOLECULES (& MOLECULAR MARKERS)

ANTIBODY DRUG CONJUGATES & RADIO-IMMUNOCONJUGATES

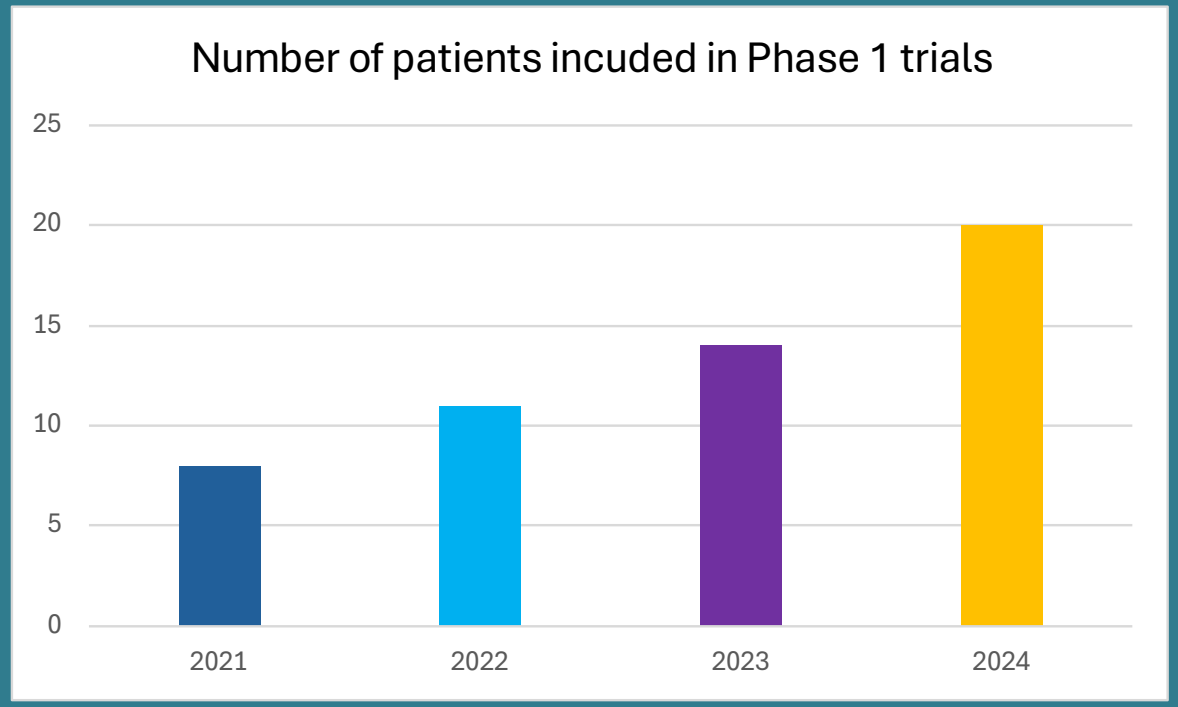
Expertise in RNA-therapeutics

REGION SKÅNE

TRACK RECORD

Increased number of early phase trials

Increased inclusion and broader tumor type inclusion



CONTACTS

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Head Early Phase Johan Olsson (Research Nurse)	Johan.I.Olsson@skane.se
Feasibilities Early Phase Team Clinical Trial Unit	klinforsk.onkologi.sus@skane.se