

A map of Europe with Sweden highlighted in dark blue. The rest of the landmasses are in a light grey color. A thin yellow line outlines the coast of Sweden. A horizontal yellow bar is located above the text.

PHASE I AND FIH ONCOLOGY/HEMATOLOGY UNITS IN SWEDEN

V2.0: 28 Sep 2026

Sweden has four Phase I Units performing early clinical cancer trials*

All units are a part of a National network between the University Hospitals in cancer



Sahlgrenska University Hospital

Phase I Unit

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Sahlgrenska Comprehensive Cancer Centre

Skåne University Hospital

Phase I Unit

Klinforsk.onkologi.sus@skane.se

Klinforsk.hematologi.sus@skane.se

Skåne University Hospital
Comprehensive Cancer Centre



Uppsala University Hospital

Phase I Unit

Studieforfragningar-bot@akademiska.se



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AKADEMISKA
SJUKHUSET

Comprehensive Cancer Center

Karolinska University Hospital

Phase I Unit

ckc.karolinska@regionstockholm.se



Karolinska
Institutet

KAROLINSKA
UNIVERSITY HOSPITAL

Karolinska Comprehensive Cancer Center

* For adult patients

Sweden – Early Phase Clinical Trial Excellence

The Phase I Units in cancer

- ▶ Located at university hospitals within OEIC-certified comprehensive cancer centers
- ▶ Dedicated and trained staff
- ▶ Oncology and hematology
- ▶ Trials can be activated at 1-4 of our units depending on trial design
- ▶ Recruitment from all of Sweden and the Nordics

Innovation & Research Strength

- ✓ High Academic Proficiency
- ✓ Strong international research collaborations
- ✓ Highly trained healthcare professionals

Precision Medicine & Expertise

- ✓ Molecular tumor boards for fast and optimal patient matching
- ✓ Advanced pathology and leading clinician-investigators

Advanced Medicine at all centres

- ✓ JACIE-accredited ATMP centers
- ✓ State-of-the-art nuclear imaging with drug distribution and pharmacodynamics

Collaborative Network

- ✓ National network: NASTRO
- ✓ Efficient patient recruitment and referrals between the units and other hospitals

The four Phase I Units in joint numbers



Capture area

- ✓ Sweden (10.7 million)
- ✓ Nordic Region (28.3 million)
- ✓ Cross-border referrals
 - Possible (if approved by sponsor)



Phase I trials open for inclusion

35



Patients included in Phase I trials

117

High standards



Collaborations

- ✓ National database for trials open for inclusion
- ✓ Collaborations with academia, biotech and big pharma
- ✓ - Advisory capabilities for biotech and small pharmaceutical companies
- ✓ Dedicated pharmacy team for IMP handling



Availability

- ✓ Situated within University hospitals
- ✓ 24/7 ICU and ER
- ✓ Multidisciplinary trial matching
- ✓ Diverse study population
- ✓ National registers — no lost to follow-up
- ✓ Certified and temperature controlled equipment



Efficacy

- ✓ High recruitment reliability for available slots
- ✓ Low drop out rate
- ✓ Fast, high-quality data entry
- ✓ High English proficiency
- ✓ Cost effective
- ✓ Promote MSA (Master Service Agreements)
- ✓ Internal follow-up



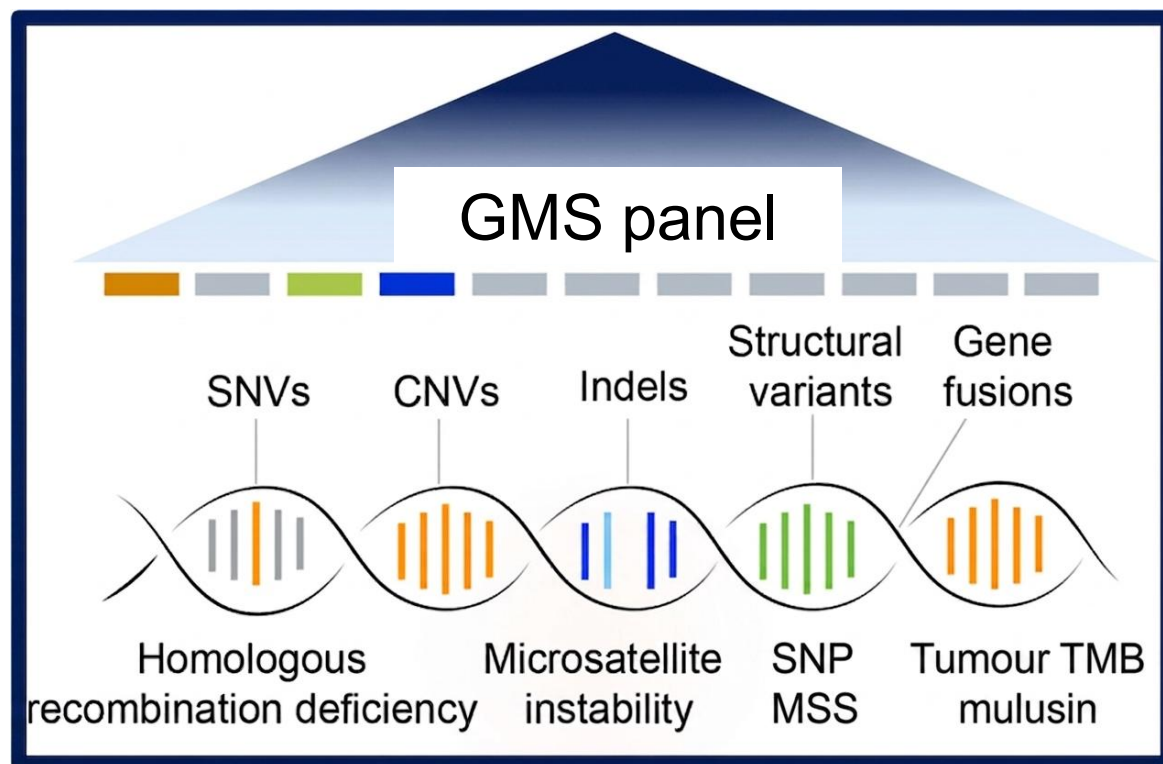
Regulatory

- ✓ Strong compliance
- ✓ Regular MPA inspections
- ✓ High quality facilities and routines, SOPs
- ✓ Available for clinical support during CTIS and Biobank submission

Broad molecular profiling and variant calling, established in all centres;

National Molecular Tumor Board for patients with advanced cancer

Genomic pipeline: from tumor analysis to treatment decision



[Solid tumours |](#)

[Genomic
Medicine
Sweden](#)

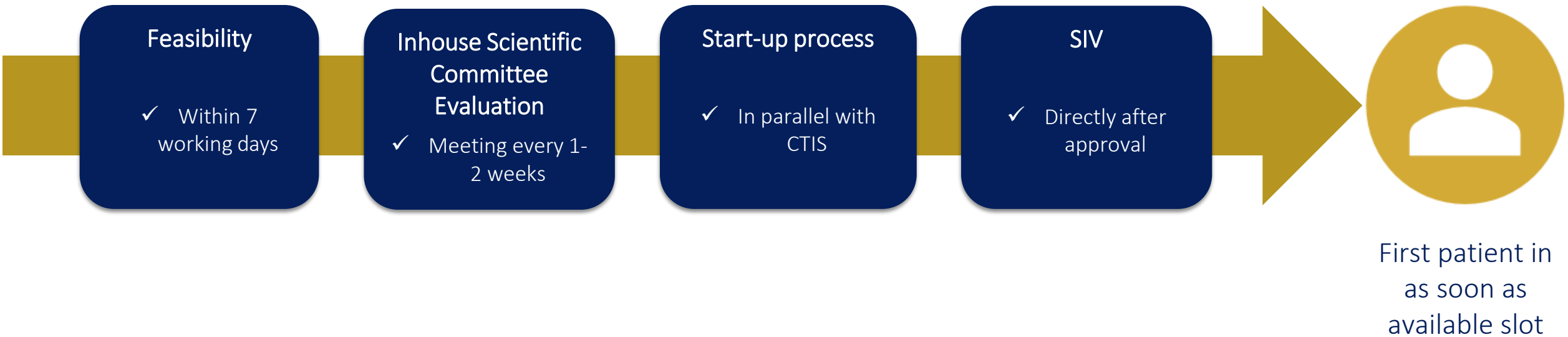


[Hematology |](#)

[Genomic
Medicine
Sweden](#)



Start-up process



Phase I Unit Uppsala (Sweden) Uppsala University Hospital



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PHASE 1 UNIT STOCKHOLM (SWEDEN)



Department of
Clinical Cancer Studies



Karolinska Comprehensive Cancer Center

Unit specific slides will now follow

PHASE I UNIT GOTHENBURG (SWEDEN)



Skåne University Hospital
Comprehensive Cancer Centre



EARLY PHASE CLINICAL TRIALS UNIT

DIVISION HEMATOLOGY, ONCOLOGY, RADIATION PHYSICS
SKÅNE UNIVERSITY HOSPITAL COMPREHENSIVE CANCER CENTER
LUND, SWEDEN



Phase I Unit Uppsala (Sweden) Uppsala University Hospital



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Uppsala University Hospital: KFUE Phase I Unit



Reach: Referrals from all of Sweden for Phase I trials, via national multidisciplinary teams

Patients: 700 000 patient visits in oncology per year

Established Research Ecosystem: Collaborations with PET-center, Theranostic center, ATMP-center, SciLifeLab, Uppsala University

Expertise: FIH (First in Human) and Phase I studies have been conducted since **2000** within the Dept. of Oncology, Hematology and Endocrine Tumors CoE.

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

Competence, Capabilities, Collaborations



Phase I team in ONK and HEMA

- 10 Phase I Investigators; 4 investigators within Hematology and 6 investigators in Solid Tumors
- 2 Medical Leads
- 6 nurses/coordinators
- 2 assistant nurses



Pre-approved for FiH

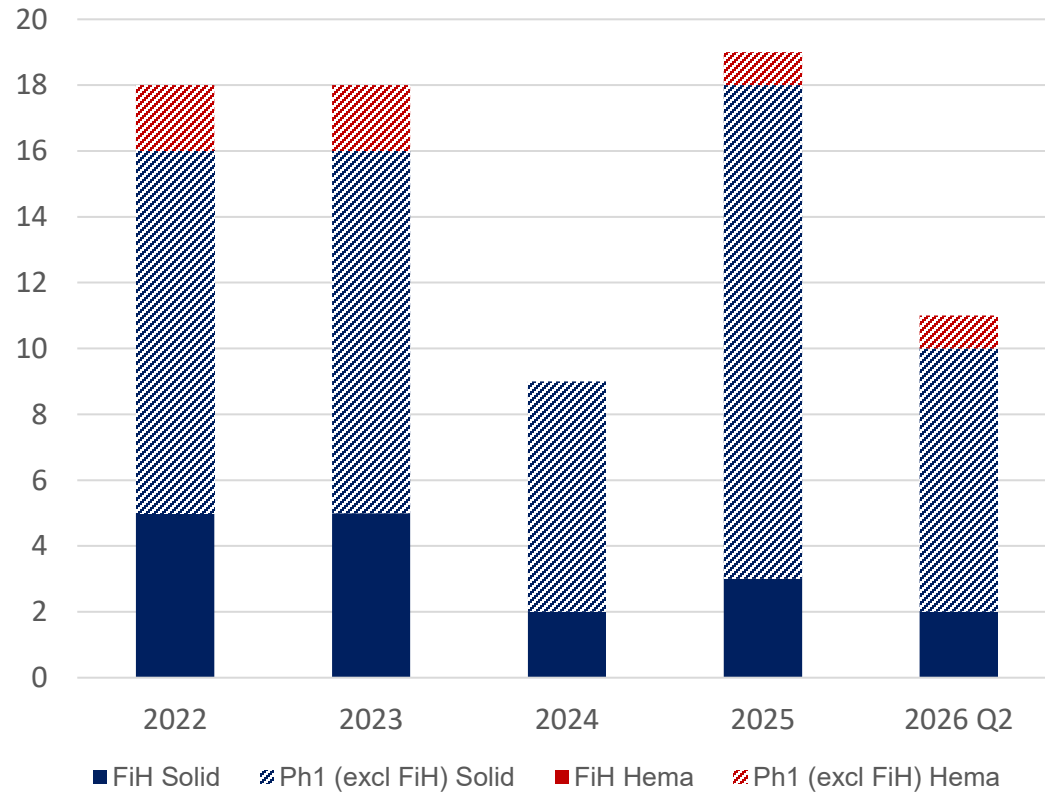
- Regularly inspected by MPA for FiH approval
- 3 beds pre- approved



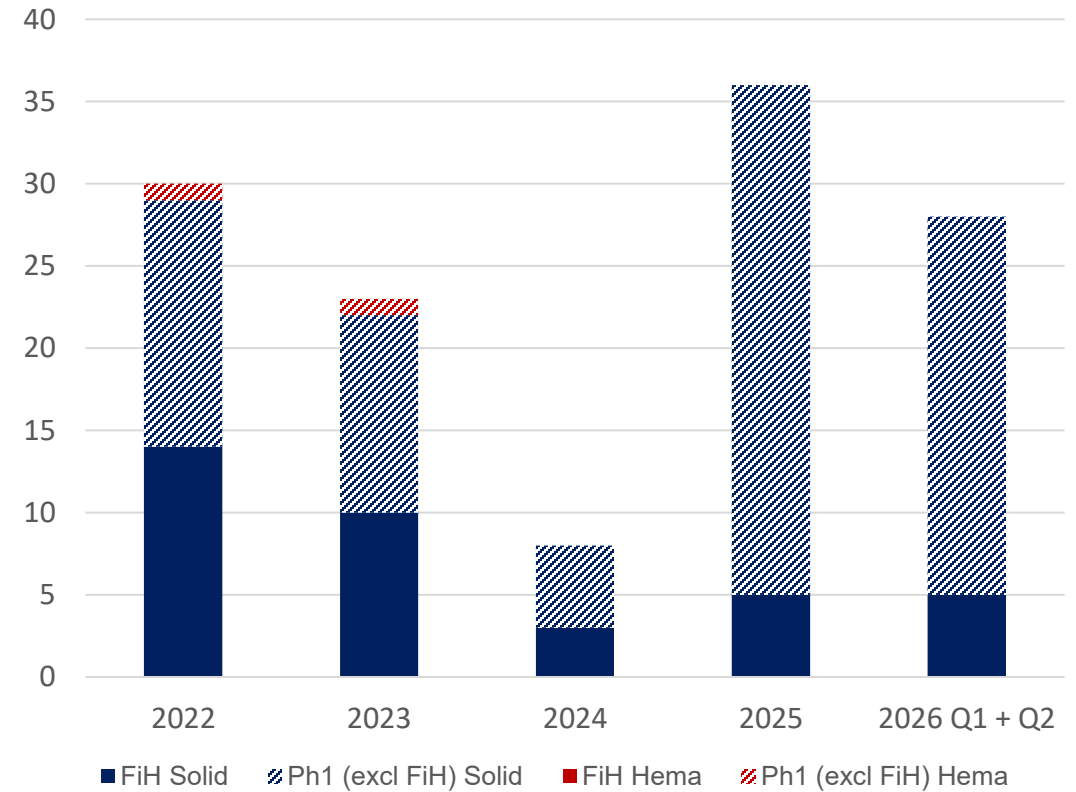
Collaborations

- Own Hospital Pharmacy department with great clinical trial expertise
- Decentralized trials (DCT)/components can be utilized in the Unit

Ongoing Phase 1 trials



Included patients in Phase 1 trials





PHASE I UNIT STOCKHOLM (SWEDEN)



Department of
Clinical Cancer Studies



**Karolinska
Institutet**



Karolinska Comprehensive Cancer Center

Karolinska University Hospital

Department of Clinical Cancer Studies

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



- **Ranking:** The best European hospital and the fourth best in the world (by Newsweek 2026)
- **Reach:** Serving the Stockholm region with over 2 million inhabitants
- **Recognition:** Highly specialized care for national and international patients
- **Established Research Ecosystem:** A strong collaboration with Karolinska Institutet, Precision Medicine Center, ATMP-center and Theranostics Trial Center
- **Portfolio:** Over 400 ongoing clinical studies for cancer patients in different phases within oncology and hematology
- **Early Phase:** Around 40 ongoing Phase I cancer trials
- **Expertise:** Dedicated unit for all types of early clinical cancer trials since 2010
- **Precision Medicine:** Local Molecular Tumor Board in cancer run through the Phase I Unit since 2021. Nordic MTB network

Competence, Capabilities and additional Collaborations

Experience across a broad range of early clinical trials



Dedicated Phase I Team in oncology and hematology

- 7 Phase I investigators with expertise in oncology or hematology, 16 additional investigators with Phase I competence
- 16 experienced study nurses/study coordinators
- 7 blood and tissue sampling coordinators/assistant nurses



Patient recruitment

- 25 referrals per week directed to Phase I
- 40% from other hospitals nationwide
- Possibilities for cross-border recruitment



Pre-approval for FiH

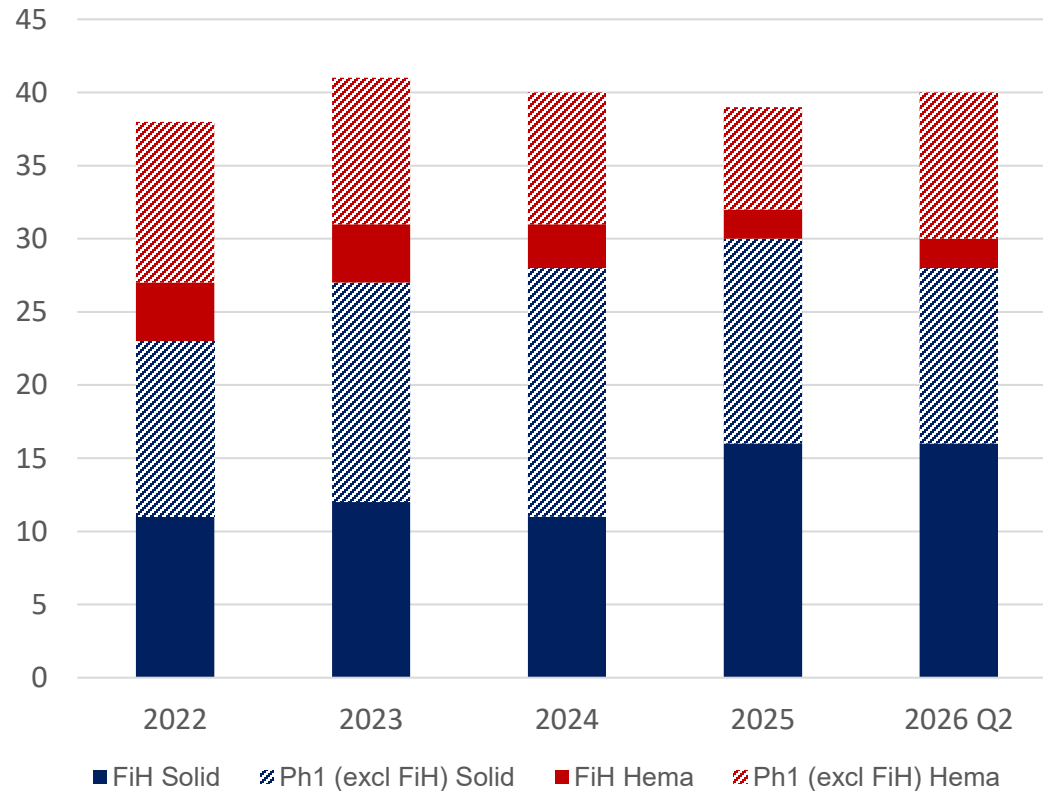
- Regularly inspected by MPA for FiH pre-approval
- Since 2012
- 17 beds pre-approved
- ICU within hospital



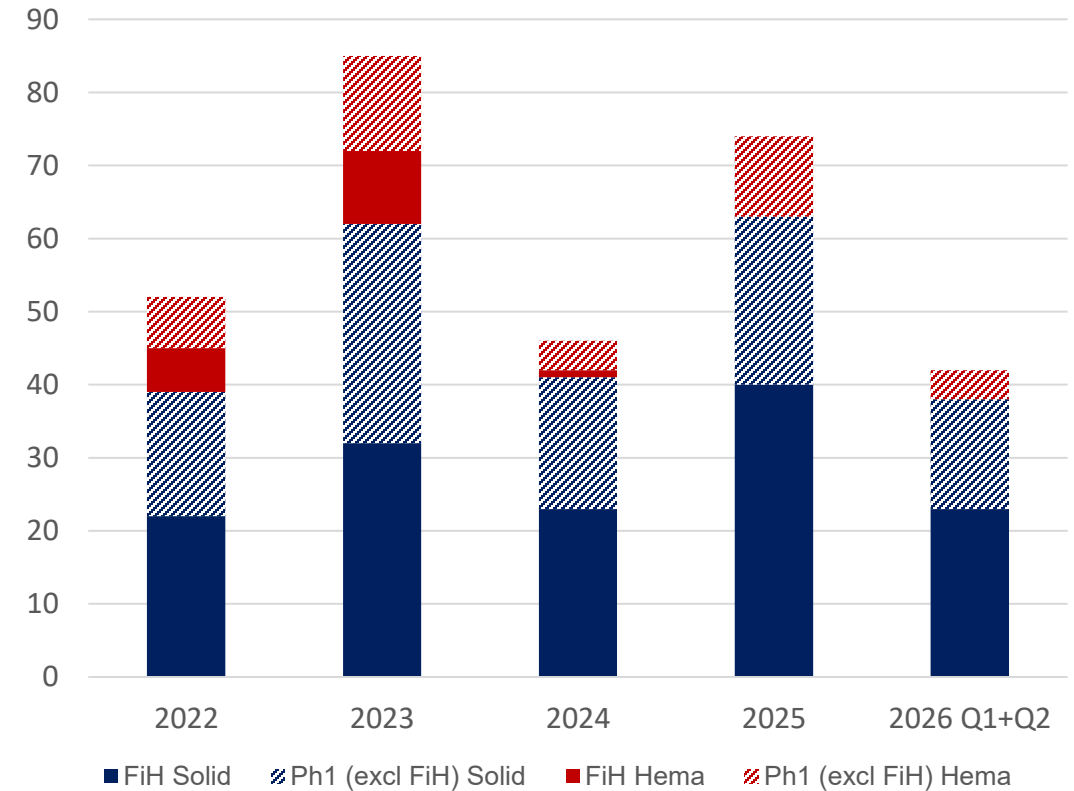
Cancer Core Europé

- Network of 7 European cancer centers: NKI, Gustave Roussy, VHIO, Heidelberg, Cambridge, INT Milano and KI
 - MTB
 - Early clinical trials

Ongoing Phase I trials



Included patients in Phase I trials



Phase I Units, Department of Clinical Cancer Studies www.karolinska.se/ckc
 Feasibility: ckc.karolinska@regionstockholm.se
 Official price list: [Forskningsprislister \(karolinska.se\)](http://Forskningsprislister.karolinska.se)

PHASE I UNIT GOTHENBURG (SWEDEN)



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Sahlgrenska
Academy

Sahlgrenska Comprehensive Cancer Centre

Integrated Infrastructure for First-in-Human Trials



CATCHMENT & RECRUITMENT

1.7 million catchment population

Phase I Unit (since 2010)

National referral network across Scandinavia

National specialized care assignments



CLINICAL CAPACITY & INFRASTRUCTURE

~215 ongoing clinical trials in cancer (FIH/Phase I-III)

Two dedicated clinical trial units

Comprehensive oncology and hematology research programs

End-to-end ATMP infrastructure

EUSOMA-certified Breast Cancer Center



PRECISION MEDICINE & DIAGNOSTICS

GMS560 panel integrated in routine and trials

Routine NGS profiling across major cancers

Advanced diagnostics embedded in clinical workflows



TRANSLATIONAL RESEARCH EXCELLENCE

National and international research infrastructures

Leading preclinical research in molecular biology, cancer genetics, and immunotherapy

Strong bench-to-bedside translational pipeline



STRATEGIC COLLABORATIONS

Leading collaborations in immunotherapy and radionuclide therapy

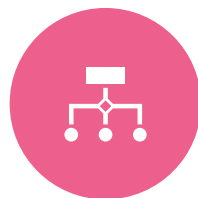
Integrated cancer research system:

- Sahlgrenska Center for Cancer Research
- Sahlgrenska Life
- Genomic Medicine Sweden
- Sahlgrenska Precision Medicine Center
- ATMP Center

Clinical Trial Unit Phase I/FIH



10 experienced Phase I investigators within hematology and solid tumours
Four Medical Lead Directors



19 research nurses/study coordinators, of whom four are dedicated to the Phase I Unit
Two assistant nurses



Resources available for 24/7 on call



Dedicated beds in lead-lined room are available for FIH studies



50 treatment beds available for clinical trials at the Department of Oncology



Recruitment is primarily via referrals, often after case presentations at regional and national Multi-Disciplinary Conferences, and national collaborations



Authorized for FIH trials by the MPA, subject for regular inspections

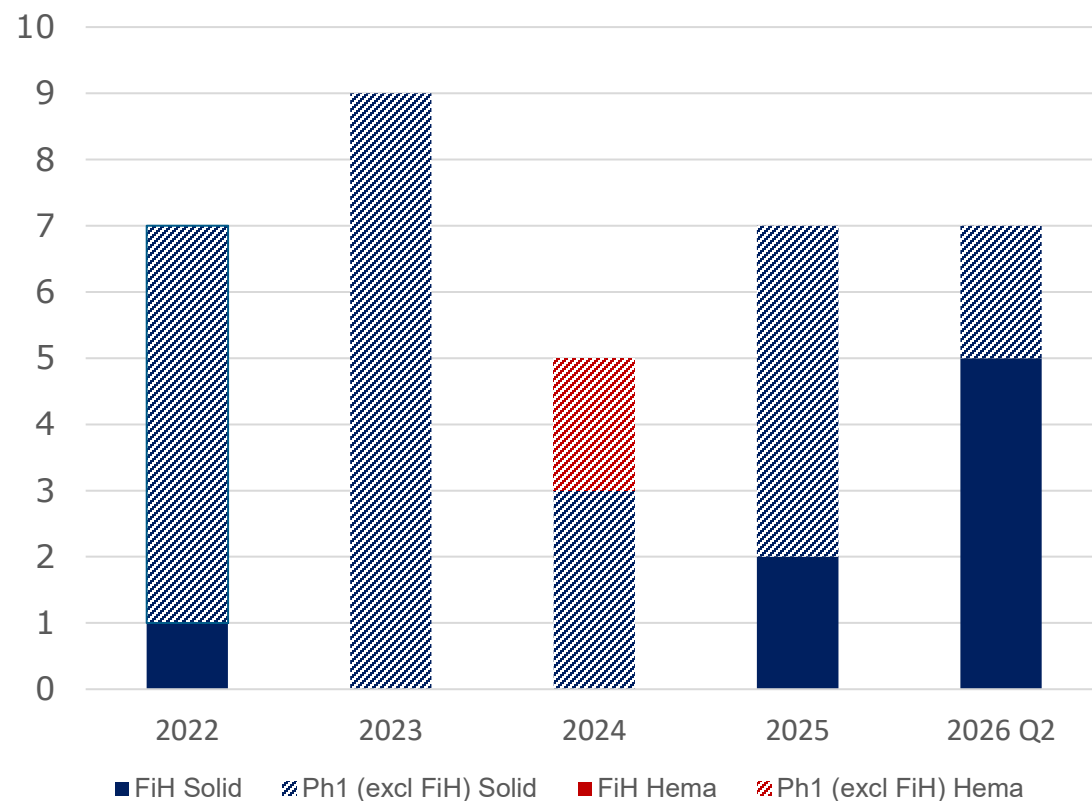


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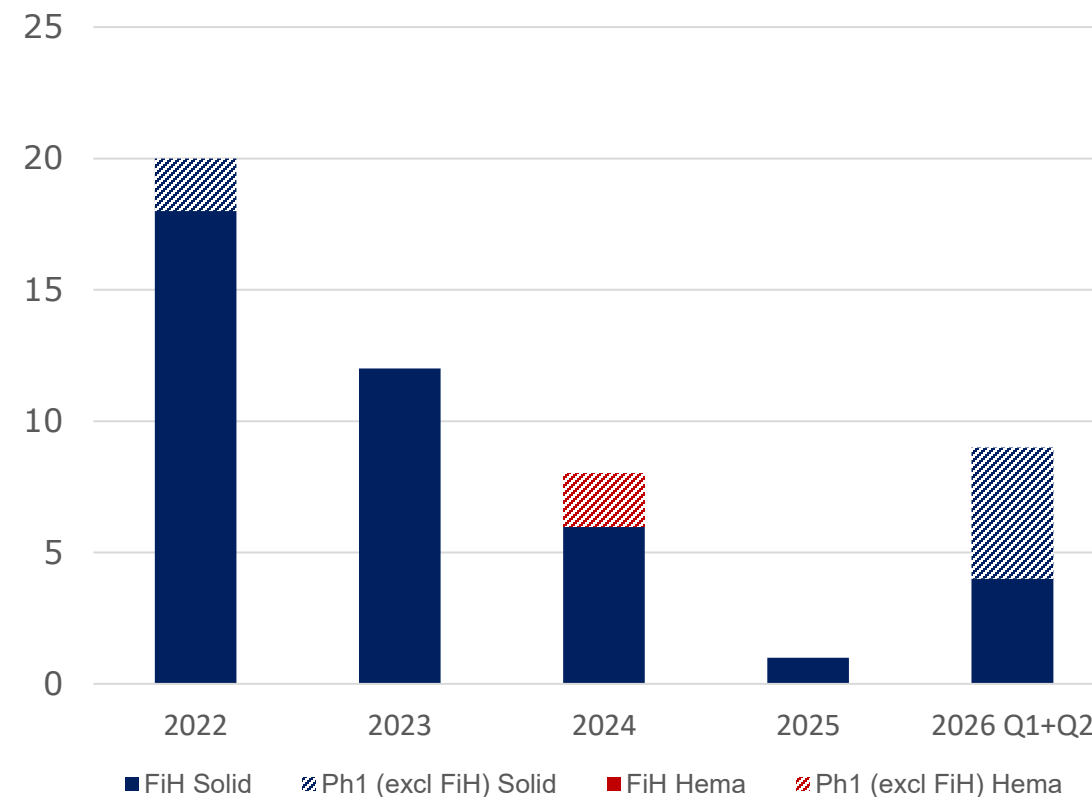
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Sahlgrenska Comprehensive Cancer Centre

Ongoing Phase I trials



Patients included in Phase I trials



Phase 1 Unit, Department of Oncology

Feasibility: su.onk.ctu@vgregion.se

Official pricelist: [Forskningsprislister - Sahlgrenska Universitetssjukhuset](#)

EARLY PHASE CLINICAL TRIALS UNIT

DIVISION HEMATOLOGY, ONCOLOGY, RADIATION PHYSICS
SKÅNE UNIVERSITY HOSPITAL COMPREHENSIVE CANCER CENTER
LUND, SWEDEN



Skåne University Hospital

Early Phase Unit

Department of Hematology, Oncology and Radiation Physics

Skåne University Hospital
Comprehensive Cancer Centre



Lund University Cancer Centre

- Strong translational research programmes
- Close integration between laboratory and clinic
- Leading immunotherapy and translational oncology research

Skåne University Hospital

- Comprehensive Cancer Centre
- ATMP centre
- Precision Medicine Centre

The Early Phase Team of the Clinical Trials Unit within the Department of Hematology, Oncology and Radiation Physics is dedicated to oncology and hematology clinical trials.

For early phase studies in other therapeutic areas, please contact the Clinical Trials Unit at Skåne University Hospital via Forum South.



Skåne University Hospital

Skåne University Hospital
Comprehensive Cancer Centre



Early Phase Unit

Department of Hematology, Oncology and Radiation Physics

- Catchment area of approximately 3 million inhabitants across South Sweden
- National referral network and possible international referrals
- All oncology and hematology diagnoses
- Dedicated Early Phase team (nurses and physicians)
- JACIE ward and ICU access
- Dedicated laboratory and pharmacy
- Dedicated feasibility contact with 7-day feasibility turnaround
- Target study activation within 100 days

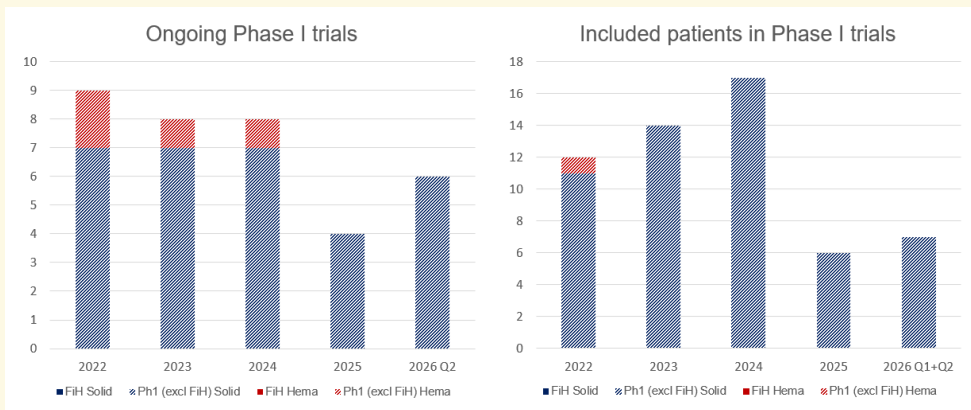


Skåne University Hospital

Early Phase Unit

Department of Hematology, Oncology and Radiation Physics

Skåne University Hospital
Comprehensive Cancer Centre



The reduction in 2025 reflects closure of trials/cohorts and delayed transition to new portfolio.

Recruitment performance above target.

Immunotherapies

- Bispecific antibodies
- T-cell engagers
- Intratumoral therapies

Advanced Therapies

- CAR-T, Cell Therapy
- Gene Therapy
- mRNA therapeutics

Precision Oncology & ADCs

- Molecular profiling
- Biomarker driven trials
- Antibody-drug conjugates

Future Development

- Pipeline of upcoming trials
- Cell therapy manufacturing

Collaborative Network

- National collaborations
- Nordic collaborations



Contact details

All units are a part of a National network
between the University Hospitals in cancer

NASTRO
NÄTVERKET FÖR UNIVERSITETSSJUKHUSENS PRÖVNINGSENHETER INOM ONKOLOGI & HEMATOLOGI



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