

START Pediatrics

Phase 1 to Phase 4 clinical trials

Introduction

HM-START Pediatrics is a Pediatric and Adolescent Clinical Trials Unit led by Dr. Marta Osuna. It serves as the pediatric branch of **START Madrid-CIOCC (Clara Campal Comprehensive Cancer Center)**, directed by Dr. Emiliano Calvo and based at HM Sanchinarro, approximately 20 minutes away. HM-START Pediatrics is integrated into the **Pediatric and Adolescent Hematology and Oncology Department of HM Hospitales**, under the leadership of Dr. López-Ibor.

Located at HM Montepríncipe, the Unit provides specialized care for patients aged **0–18 years** from within the HM Hospitales network as well as those referred from other centers across Spain and internationally. All non-clinical activities — including data management, contracting, and monitoring — are managed centrally by the START Madrid-CIOCC teams, of which START Pediatrics is an integral extension.

HM Hospitales: a network that fosters excellence

START Pediatrics is an integral part of HM Hospitales, one of the most prominent private hospital groups in Spain in terms of size, healthcare capacity, and commitment to innovation. The network includes **54 centers** —23 of them hospitals— with more than **110,000 annual admissions**, approximately 1.4 million outpatient visits, and a very high diagnostic workload: over 14 million laboratory tests and 1.7 million radiology studies per year.

Pediatric Hematology and Oncology Department of HM Montepríncipe

With more than 20 years of history, the Pediatric Hematology and Oncology Department of HM Montepríncipe is the **largest private pediatric hematology and oncology center in Spain**. It was founded and is led by **Dr. López-Ibor**, who has over 40 years of experience in pediatric hematology and oncology.

The Department treats children and adolescents from **birth to 18 years of age**. Patients **older than 18 years** with tumors typically diagnosed during childhood may also be treated. The care model is **patient- and family-centered** and is supported by a multidisciplinary team tailored to each patient's needs.

The Department is equipped with all the technical and human resources required of a **top-level Pediatric Oncology Department**: pediatric and adult medical specialties, pediatric and adult surgeons, pediatric and adult radiologists and neuroradiologists, a third-level Intensive Care Unit dedicated to newborns, children, and adults, Radiotherapy, Nuclear Medicine, and a comprehensive Laboratory Service including Hematology, Blood Bank, Autologous Bone Marrow Transplantation, Genetics, Molecular Biology, Therapeutic Targets, and Pathology. The Department holds both internal and joint **multidisciplinary committees** with adult specialists, including solid tumor boards, CNS tumor boards, Molecular Tumor Board, oncology clinical sessions, and clinical trial committees.

As the pediatric branch of HM CIOCC, **collaboration with adult oncologists** and the Medical Oncology program is close and direct. Adolescents, young adults, and pediatric patients with adult-type tumors are **jointly managed** by pediatric oncology and medical oncology teams.

The Pediatric Hematology and Oncology Department of HM Montepíncipe is the **reference center** for pediatric oncology within the HM Hospitales network, treating patients diagnosed with any oncological condition across the 23 HM Hospitales centers throughout Spain. In addition, when an oncological diagnosis is made in a private hospital outside the network, referring physicians frequently contact the Department to coordinate patient transfer.

The Department treats patients covered by **private insurers, mutual insurance systems, self-pay patients, and international patients**.

- ✓ **More than 35% of the Spanish population holds private health insurance.**
- ✓ Approximately 15% of Spain's population are civil servants or public-sector employees. Of these, around **65% choose private healthcare** as their primary source of care through mutual insurance systems such as MUFACE, ISFAS, or MUGEJU. This represents approximately **2.3 million** people in Spain whose primary access to healthcare is **exclusively through private insurance**.
- ✓ For self-pay patients, a **specific pediatric oncology pricing scheme** is in place to ensure treatments remain as accessible as possible. Treatment is provided at no cost for patients enrolled in clinical trials.
- ✓ There are no restrictions on **treating patients from any country**, and patients from all over the world are welcome. The center has an **International Department** that supports international patients throughout their care pathway, including administrative procedures and translation services during medical consultations. For families traveling from outside Madrid, free accommodation near the Department is available, including housekeeping services (family coordination, meals, and cleaning). In selected cases,

donations from benefactors through the HM Foundation help cover treatment or specific patient needs.

START: a global platform dedicated to early-phase trials

START corporate is the **leading global organization** fully dedicated to **early-phase oncology clinical trials**. With a presence in the United States and Europe, START operates 15 sites, manages more than 800 active studies, and has directly contributed to the approval of over 45 drugs by regulatory agencies such as the FDA and EMA.

START's value proposition is based on highly experienced clinical researchers, standardized processes across sites, and a strong reputation among sponsors, pharmaceutical companies, and CROs.

START's centralized operating model **accelerates** protocol review, feasibility assessments, and multi-site activation, achieving highly competitive start-up timelines. In most cases in which the network is selected, START is the first site to open the study, enabling early patient access and the generation of high-quality clinical data.

START centers are certified Phase I Centers of Excellence. The **regulatory compliance** record is outstanding, with more than 175 sponsor audits conducted over the past 15 years and no critical findings.

START also supports patients throughout the entire clinical trial process through the **START Hope Hub**, which assists patients and healthcare professionals in identifying available trials, facilitating pre-selection and navigation of inclusion criteria. START also provides clear information, logistical support, and guidance during treatment.

START Madrid–CIOCC

START Madrid–CIOCC is part of the Clara Campal Comprehensive Cancer Center (CIOCC). Founded in 2008 by Dr. Emiliano Calvo, it was the **first START site** in the European Union. Today, START Madrid–CIOCC has more than 150 early-phase clinical trials open and treats over 300 new patients per year, making it one of the **largest recruiting** centers in Europe and worldwide.

START Madrid–CIOCC was the first and only site accredited under the regulations of the Community of Madrid, highlighting the **leadership** of the private sector in clinical research.

Through its adult Hematology and Pediatric branches, including START Pediatrics, it is **the only program worldwide capable of treating patients of any age and with any type of malignancy.**

START Pediatrics: from Phase 1 to Phase 4 clinical trials in pediatric Hematology and Oncology patients

START Pediatrics **integrates** all the advantages described above and operates under unified START quality and safety standards. As the pediatric arm of START Madrid–CIOCC, its working methodology and SOPs are identical, and all central services (start-up, contracts and budgets, implementation, marketing, legal, IT, quality, compliance, study acquisition, etc.) are shared.

Clinical Infrastructure:

START Pediatrics meets **all the requirements** of an **excellent Phase 1 to Phase 4 clinical trials unit**, including a **dedicated and fully equipped pharmacy** for the management of investigational medicinal products, with a clean room and biological safety cabinet, dedicated consultation rooms, treatment chairs, and an **on-site laboratory**. The laboratory performs same-day testing and includes -80°C and -20°C freezers with continuous temperature monitoring.

The Unit also features a **dedicated procedure room** to avoid transferring patients to the operating theater for minor procedures (biopsies, bone marrow aspirations, lumbar punctures, post-surgical wound care under general anesthesia, etc.).

Two specialized rooms (“**Onco-ICU**”) with positive-pressure isolation, continuous remote monitoring, and optional video surveillance allow the management of critical situations without transferring patients to the ICU. When necessary, patients have access to neonatal, pediatric, and adult third-level ICUs.

The Unit also includes an **on-site school** for patients from early childhood through university level, operating Monday to Friday from 9:30 to 14:00, available to both inpatients and outpatients. The HM Montepríncipe School is officially recognized by the Community of Madrid and staffed by teachers specialized in all educational stages.

Additional **dedicated areas** include:

- “El Bosque”: an outdoor area with picnic areas, swings, sports facilities, and family-friendly areas, supervised by nursing staff.
- Age-adapted playrooms.
- A teen lounge.
- A parents’ room for working, socializing, or meals.

Non-clinical Infrastructure:

START Pediatrics operates within the same advanced non-clinical infrastructure shared with START Madrid–CIOCC, providing a **fully paperless environment** that reflects a strong commitment to innovation, efficiency, and data integrity. All essential documentation is digitally managed, with immediate access to scanned source documents, ensuring traceability, transparency, and real-time availability for study teams and sponsors.

The infrastructure supports modern clinical research through **remote monitoring** capabilities, including full *DMV with SDV*, enabling secure and efficient oversight without the need for constant on-site visits. This digital ecosystem streamlines workflows, accelerates decision-making, and guarantees the **highest standards** of quality and compliance, positioning START Pediatrics as a forward-thinking center at the forefront of non-clinical and clinical research operations.

Staff

The team at START Pediatrics has been **directly trained by START-CIOCC** personnel. The medical and nursery team are fully dedicated and highly experienced. START Pediatrics has dedicated medical and nursing staff, study coordinators, pharmacists, and data managers. All staff are familiar with and involved in the care of every patient.

Pharmacokinetics personnel are **IATA-certified** and capable of daily specimen shipments. Regulatory Affairs and Data Management ensure compliance with FDA guidelines, GCP, and manage platforms such as Medidata RAVE, InForm, and Veeva. All personnel are current on good clinical practice guidelines.

The Unit also includes its own support **multidisciplinary** staff: physical therapist, psychologist, social worker, secretary, visual-thinking art specialist, volunteers, and spiritual care.

Patients

START Pediatrics treats patients from **birth to 18 years of age**, as well as patients of **any age** with tumors typical of childhood. The Unit accepts patients with private **insurance, civil servant mutual insurance schemes, self-pay patients, and international patients**. Within clinical trials, treatment is provided at **no cost to the patient**, even in the absence of private insurance, despite being a private hospital.

Services & Logistics

Patients have access to a **24/7** telephone line, **365 days a year**, staffed by the Unit's own pediatric oncologists. In emergency situations, patients are always treated directly within the Unit and not through the Emergency Department.

When required, **palliative care** is provided by the same medical and nursery team. Palliative care plans are flexible and individualized and can be delivered at home, in the hospital, or in a combined setting.

Research

START Pediatrics integrates clinical care with **advanced preclinical and translational research** capabilities, including START Patient-Derived Xenografts program of animal models (**XenoSTART**), enabling rapid translation of laboratory hypotheses into patient-centered clinical trials. Close collaboration with the global START network provides access to emerging technologies and a diversified clinical trial portfolio.

Conclusion – Why START Pediatrics?

- START Pediatrics offers extensive clinical experience and conducts **all types of studies, from Phase I to Phase IV, in pediatric hematology and oncology patients**. It is an integral part of START Madrid–CIOCC, a leading organization in clinical trial development, with close collaboration with adult medical oncology and Phase I units. The non-clinical operations are run together with START-Madrid CIOCC.
- As **part of START**, the leading international network accelerating therapeutic innovation, START Pediatrics benefits from **robust, standardized, and high-quality processes**. The Unit is staffed by a highly trained, fully dedicated **multidisciplinary specialized and fully-dedicated team** available 24/7, year-round.
- START Pediatrics provides access to a unique patient population with significant unmet medical needs, including **privately insured patients, self-pay patients, civil servants, and international patients, with nationwide reach** across Spain and worldwide.
- The Unit has the ability to treat **children of any age with any type of oncological or hematological malignancy, including adolescent and young adult patients**, a population that is often difficult to identify and recruit for clinical trials.
- Patients enrolled in clinical trials receive **treatment at no cost**, even without private insurance.
- **Comprehensive multidisciplinary care** is provided through collaboration across all pediatric and adult specialties and access to all treatment modalities, including chemotherapy, radiotherapy, radionuclide therapy, autologous transplantation, immunotherapy, and CAR-T cell therapy. Patients also benefit from access to neonatal, pediatric, and adult third-level ICUs.
- The Unit features an integrated procedure room, an on-site school covering all educational levels, age-adapted spaces, outdoor recreational areas, and a **comprehensive supportive care program for patients and families**, including Child Life services, psychology, social work, physiotherapy, visual-thinking art, spiritual care, and dedicated volunteers.
- **Free accommodation near the Department** is available for eligible families, including housekeeping services.