
HiRO
Expanding Our European Reach: Aixial's Deep EU Footprint Now Powers HiRO

INTRODUCTION

HiRO's acquisition of the CRO division of Aixial brings an established, deeply rooted European clinical research presence into our global network, one built over more than 25 years of continuous operations across the continent.

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A European Foundation Built Over Decades

Aixial's CRO heritage in Europe is foundational, not recent. Originating in France as part of the ALTEN Group, Aixial developed physical office presence in the United Kingdom, Ireland, and Romania, with clinical professionals working across both Western and Eastern Europe. This distributed model was deliberately built to span the continent's diverse regulatory environments, patient populations, and site ecosystems — not concentrated in a single hub, but embedded across the markets that matter most to sponsors.

This network was further strengthened through the acquisition of Cmed Group, a UK-based, technology-led CRO with more than two decades of experience in oncology, immuno-oncology, cell therapy, and rare diseases. The result is a pan-European infrastructure with the depth to support sponsors from first study contact through regulatory submission and approval.

Operating in full compliance with ICH-GCP standards, HiRO's EU team delivers clinical research services to the highest quality benchmarks expected by EMA regulators and major pharmaceutical and biotech sponsors.

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What the EU Footprint Delivers for HiRO Clients

The breadth of HiRO's EU team capabilities — integrated into HiRO's global service offering — spans the full spectrum of clinical development:

Clinical Operations

Monitoring, project management, site management, and study start-up across multiple EU jurisdictions, with experienced in-country professionals who understand local regulatory requirements, ethics processes, and site dynamics — including EU CTR and CTIS workflows.

Pharmacovigilance

HiRO's EU team pharmacovigilance specialists have supported over 160 studies across Europe, including product approvals from early phase through NDA, with particular expertise in EU Clinical Trial safety submissions.

Biometrics and Data Science

Statistical analysis, biostatistics, data management, CDISC programming, and medical writing delivered by a team with deep European regulatory knowledge.

Regulatory Affairs

EU-focused regulatory strategy and submissions, with specialists navigating the EMA ecosystem and the country-specific requirements that vary meaningfully across member states.

Technology-Enabled Oversight

HiRO's EU team operates within HiRO's globally standardized technology framework — the HiRO Linkage™ Approach — which connects people, systems, processes, oversight, data, and collaboration into a unified study experience. Sponsors gain real-time visibility, audit-ready documentation, and consistent data quality across every European market where their study runs, backed by the same biometrics-led discipline that defines HiRO's global operations.

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Therapeutic Expertise Proven Across Europe

HiRO's EU team has accumulated a track record in the therapeutic areas where clinical complexity is greatest. With over 300 oncology studies completed across Europe, North America, and Asia-Pacific — and up to 150 neurological studies conducted globally — the team brings specialized depth in:

Oncology and Immuno-Oncology
including complex dose escalation, biomarker-driven, and crossover trial designs

Central Nervous System (CNS)
a therapeutic area requiring nuanced protocol design and deep site relationships

Rare Diseases
where patient identification and site selection demand both scientific rigor and European network reach.

Dermatology
supporting early-phase and adaptive study designs across global regions.

Radioligand Therapy (RLT) and Radiopharmaceuticals
where isotope logistics, radiation safety requirements, and specialized site capabilities demand both operational precision and regulatory rigor across European markets.

Cell and Gene Therapy
reflecting the growing intersection of advanced modalities and EU regulatory evolution.

This therapeutic track record spans Phase I through Phase IV, including First-in-Human trials and Real-World Evidence studies, giving HiRO clients seamless access to European expertise at every stage of development.

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A Strategic Bridge Between Europe and the World

For HiRO's core clients — Asian biotechs expanding into Western markets, and US and European sponsors seeking broader global trial reach — HiRO's EU platform provides a critical bridge. European regulatory acceptance of data, access to diverse patient populations, and alignment with EMA requirements often form an essential part of global development strategies.

By integrating HiRO's established EU capabilities with our strengths across Asia-Pacific and North America, we now offer sponsors a genuinely connected global CRO experience: consistent operational standards, unified data science capabilities, and regional expertise that does not require sponsors to manage multiple partner relationships across geographies.

Whether your program is entering Europe for the first time or scaling an ongoing multi-region study, HiRO brings the European depth — and the global reach — to deliver.

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