
DELIVERING EVIDENCE
WHEN IT MATTERS MOST.
iOMEDICO
Closing evidence gaps in HTA –
with regulatory-grade Real World Data

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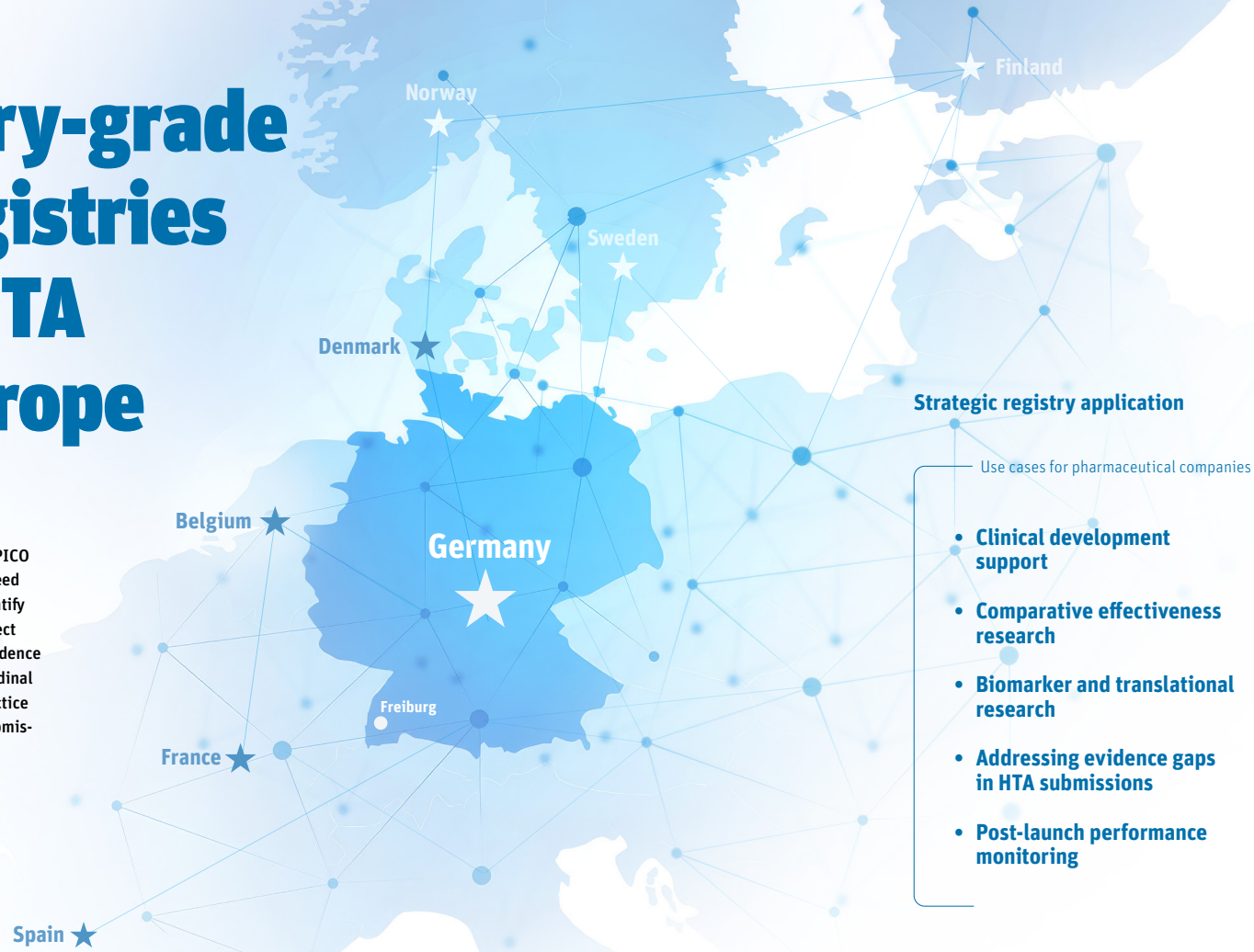
# Regulatory-grade tumor registries support HTA across Europe

**Evidence solutions tailored to your submission strategy**

Are you looking for Real-World Data to close PICO gaps in your HTA submission? Whether you need to support your appropriate comparator, quantify clinically relevant subgroups, or enable indirect treatment comparisons - regulatory-grade evidence is essential. iOMEDICO's prospective, longitudinal tumor registries adhere to Good Registry Practice (GRP) guidelines and deliver RWE for HTA submissions across Europe.




## Strategic registry application

Use cases for pharmaceutical companies

- Clinical development support
- Comparative effectiveness research
- Biomarker and translational research
- Addressing evidence gaps in HTA submissions
- Post-launch performance monitoring

# Case Studies

## 1 FAST-TRACK TO RESOLVING STANDARD OF CARE DISPUTE

A European HTA body challenged our client's trial comparator arm, jeopardizing reimbursement approval. We rapidly delivered real world treatment and effectiveness evidence from our registry. Our data resolved the dispute within weeks, securing full approval of reimbursement, and successfully averting an estimated 6-12 month market access delay.

## 2 TARGET TRIAL EMULATION WHEN RCTs ARE NOT FEASIBLE

Our client needed comparative effectiveness evidence between two breast cancer treatments but no randomized, head-to-head trial existed. We conducted a target trial emulation applying advanced causal inference methods toprovide rigorous comparative data. The peer-reviewed publication closed a critical evidence gap and strengthened our client's HTA negotiation position.

## 3 BIOMARKER PREVALENCE WHEN LITERATURE IS INSUFFICIENT

Prior to launching a novel targeted therapy, our client needed biomarker prevalence data for commercial forecasting and HTA preparations. We combined our registry's clinical data with centralized biomarker testing of archived tissue samples. This translational approach delivered prevalence estimates, treatment patterns and outcomes data that informed regulatory label discussions, pricing strategy, and provided compelling evidence of unmet medical need.

## 4 PRECISE EPIDEMIOLOGY FOR RARE SUBGROUPS – ON TIME, ON TARGET

Our client required epidemiological data on a rare, later-line patient subgroup for their benefit assessment. Published literature lacked sufficient granularity on treatment sequences and patient characteristics. We conducted customized analyses, providing precise population estimates and treatment pattern data unavailable from any other source. Delivered within weeks, our analyses supported benefit rating and reimbursement decision.

## The value of regulatory-grade, high-quality Real World Data

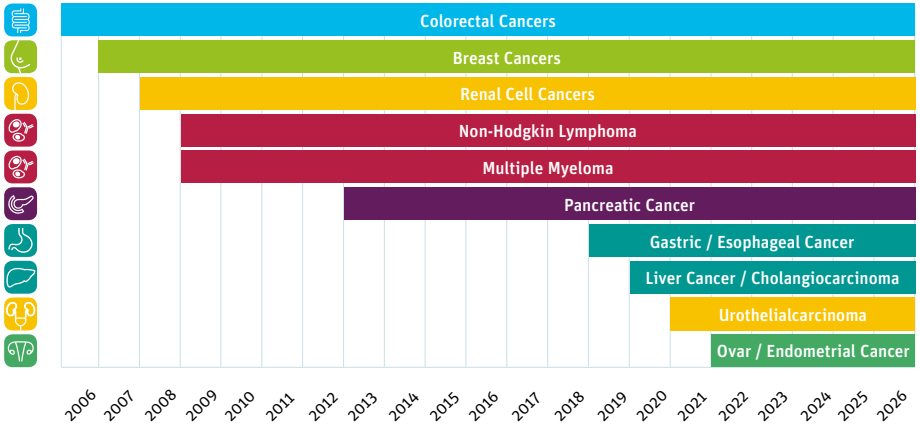
- → Representative, prospective data from initial diagnosis
- → Longitudinal follow-up across all treatment lines
- → Treatment patterns and standard of care characterization
- → External control arms and synthetic control cohorts
- → Evidence supporting HTA submissions and dossiers
- → Post-launch surveillance and evidence generation

# Comprehensive platform to address your evidence gaps

### 20 years of prospective, quality-controlled RWD collection across key tumor entities

Our platform provides access to >57,000 patient datasets from 400+ representative study sites. This extensive data set enables single- and multi-cohort analyses as well as cross-entity comparisons tailored to your specific requirements. The integrated platform combines clinical data, patient-reported outcomes, and biomarker profiles – delivering multi-dimensional evidence for your regulatory and market access strategies.

## FILLING EVIDENCE GAPS WITH LONG-TERM REPRESENTATIVE REGULATORY-GRADE RWD




| | Patients | Study Sites |
|---|---|---|
| Colorectal Cancers | > 7.700 | > 100 |
| Breast Cancers | > 10.100 | > 220 |
| Renal Cell Cancers | > 2.800 | > 190 |
| Non-Hodgkin Lymphoma | > 6.200 | > 160 |
| Multiple Myeloma | > 2.700 | > 180 |
| Pancreatic Cancer | > 2.300 | > 120 |
| Gastric / Esophageal Cancer | > 1.500 | > 150 |
| Liver Cancer / Cholangiocarcinoma | > 900 | > 110 |
| Urothelialcarcinoma | > 600 | > 190 |
| Ovar / Endometrial Cancer | > 1.400 | > 150 |

**> 57.000** patients data sets

**> 26.000** PRO data sets

**> 300** publications

# Registry Data Built for Regulatory Success

Regulatory decisions demand uncompromising data quality. iOMEDICO registries deliver – by design, from day one.

- **IQWiG-endorsed** methodology
- **Proven track record** in AMNOG oncology dossiers
- **Internationally recognized** at major conferences

**The EMA's new Data Quality Framework sets the bar. We've been exceeding it for years. Your regulatory success deserves premium registry data.**

| | Prospective iOMEDICO registry | Retrospective EHR/CHART REVIEW |
|---|---|---|
| Prospective, longitudinal data collection – full patient journey | ✓ | × |
| Standardized, structured, up-to-date, fit for purpose data | ✓ | × |
| Real-time validation & missing data <10% | ✓ | × |
| Ready for immediate analysis | ✓ | × |
| Outcomes not routinely documented (e.g. ECOG, Best Response, PROs) | ✓ | × |
| Translational analyses (e.g. prevalence of biomarkers) | ✓ | × |

**Good Registry Practice**
in accordance with EMA requirements

**External references to our registries**

- **AMNOG track record** in 25% of oncology dossiers since 2012
- **HTA support** in Europe on PICOs, SOC and effectiveness

- **ASH & EHA:** Clinical relevance designation award; other international distinctions
- **IQWiG** recommends our tumor registries MYRIAM and RUBIN

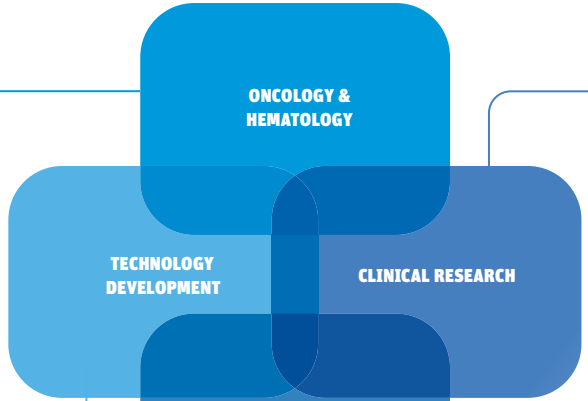
- **ASCO & ESMO Annual Meetings:** Referencing our publications at high-impact meetings
- **SISAQOL-IMI consortium** referred to our data for international guidelines on PRO standards

# About us

**Your oncology CRO partner.**

For over 25 years, we have been dedicated to oncological research. Our goal is to make effective therapies available fasterand improve tumor treatment. iOMEDICO stands for oncological science rooted in real-world.

We design research projects and connect stakeholders to advance oncological knowledge and patient care – in collaboration with the pharmaceutical industry and our physician network. Each with their expertise, each with their experience.




**ONCOLOGY & HEMATOLOGY**

In-depth institutional experience and oncological expertise across the entities and treatment options

**CLINICAL RESEARCH**

Science-driven clinical trial design and conduct powered by a large investigator network, specialized knowledge, and quality excellence

**TECHNOLOGY DEVELOPMENT**

Innovative life science-specific technology and forward-looking analytics for deep insights and real-time access to operational information

**REAL WORLD DATA**

Large and comprehensive data platforms as the basis for real evidence, market access and strategic decisions

# Connect with us

Let‘s discuss how we can
support your evidence needs.

Contact us

Visit our Website

**EU-HTA@iomedico.com** | **www.iomedico.com** | iOMEDICO AG, Ellen-Gottlieb-Straße 19, D-79106 Freiburg i. Br.

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