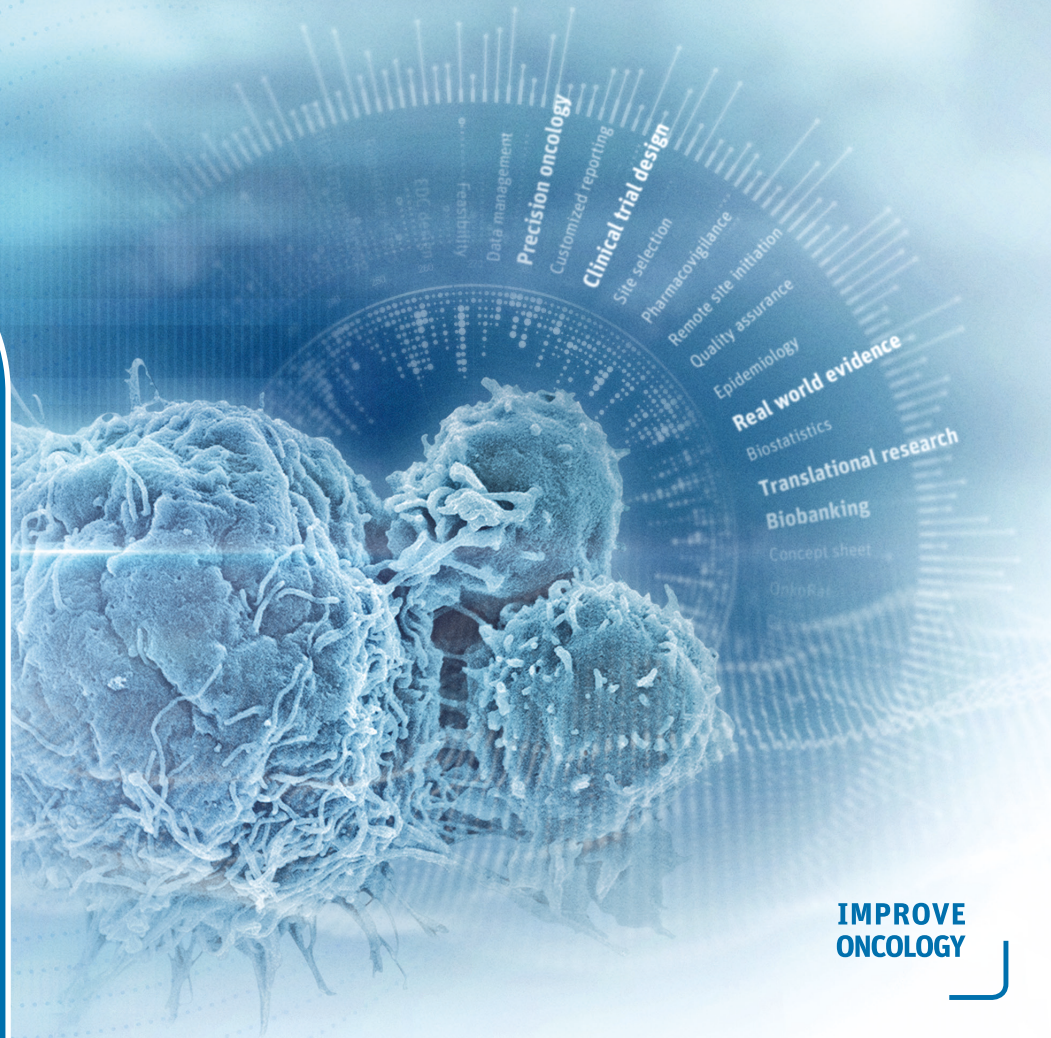
iOMEDICO

Patient-Reported Outcomes in Oncology

Quality Makes the Difference

Long-standing expertise and high-quality data meet regulatory requirements



IMPROVE ONCOLOGY

Expertise is key and makes a difference for authorities

High-quality PRO data can support regulatory success. Discover how iOMEDICO's quality-controlled approach delivers results that meet the requirements of bodies like IQWiG.

Over the last years, clinical trials in oncology, that collect patient-reported outcomes (PRO) have risen sharply. In 2011 the AMNOG defined an improvement in quality of life as a patient-relevant endpoint. For years, PROs have been included in the benefit assessment of new drugs. Both EMA and EORTC emphasize the importance of PRO as "a crucial endpoint from the HTA and payer's perspectives".[1] Still, the positive impact of PRO on regulatory assessments and HTA can become void, if data quality is not sufficient. Issues related to study design, PRO item selection, assessment frequency, study conduct or handling of missing data can dramatically reduce data quality.[1] High-level expertise is required to collect data and handle this specialized field professionally and meet authorities' requirements.

PRO excellence with international recognition

Highlighting the importance of standardized methods to handle PROs like any other trial endpoint, the SISAQOL-IMI consortium released new recommendations on PRO data collection and analysis.[2] The consortium worked for four years on the guideline and we are proud that they referred[3] to our research[4] during this process.

The high quality of our data is reflected in an oral session at ASCO 2025: Prof. Gradishar, Northwestern University Chicago, referred[5] to our PRO data[6] in his talk. The IQWiG also appreciates our work by rating our MYRIAM registry "most suitable primary data source" for application-related data collection in multiple myeloma. Our collection of PRO data and our high-quality data were given as the reasons for this outstanding rating.

PRO benefits:

- Patient-centric endpoint
- Insights into health-related quality of life
- Unbiased statements about side effects
- Assessment of the patient population
- Definition of standard of care
- Entity-specific validation of endpoints
- Supporting evidence for HTA and pricing negotiation

External References

SISAQOL-IMI consortium referred to our data during development of international guidelines on PRO standards

ASCO Annual Meeting 2025: Prof. Gradishar, NU Chicago, referenced our PRO data during an oral session

IQWiG recommends our tumor registry MYRIAM, PRO and high data quality were crucial

1. Pe M. et al. Lancet Oncol. 2025;26(6):687-690. 2. Amdal CD. et al. Lancet Oncol. 2025;26(12):e683-e693. 3. Thomassen D. et al. BMC Med Res Methodol. 2025;25(1):56. 4. Haug N. et al. Qual Life Res. 2024;33(4):1085-1094. 5. Gradishar WJ. Breast Cancer Metastatic Session; May 31, 2025; Chicago, USA. 6. Marschner N. et al. JAMA Netw Open. 20;3(3):e200643-e200643.

From PRO Pioneers to Proven Experts

From early adoption in 2002 to comprehensive PRO expertise today – iOMEDICO delivers validated longitudinal data through established quality processes.

In 2002, we collected the first patient questionnaires at iOMEDICO. Back then such a patient-centered approach was still rare in oncology clinical trials. Through this initiative, iOMEDICO pioneered valuable work that benefited the standardization of processes. The benefit of these patient-centered insights became clear quickly, and since 2013, iOMEDICO has collected questionnaires prospectively for every project, in registries often spanning many years. With our outstanding experience in PRO we deliver high-quality data that meet the requirements of regulatory bodies.

Over the past ten years, we have collected more than 230,000 questionnaires. Our database contains over 26,000 PRO data sets. This substantial amount of data allows us to perform both representative single-cohort analyses and multi-cohort analyses within one entity, as well as across different entities. The value of this large volume of data cannot be overstated.

At the same time, data quality is our top priority. We use validated questionnaires and thanks to our sophisticated logistics, we achieve response rates of over 75%.

Our PRO-services:

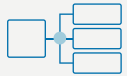
- Design of patient surveys
- Selection of suitable, validated questionnaires
- Development of questionnaires on specific issues
- Questionnaire management in compliance with data protection regulations
- Evaluation, description, and interpretation of PRO Data
- Publication

24 years of PRO experience

Experience & Foundation

Long-standing experience in PRO analysis and methodology since 2002

PRO collection in every project since 2013



Single-cohort analyses and multi-cohort analyses within one entity, as well as across different entities

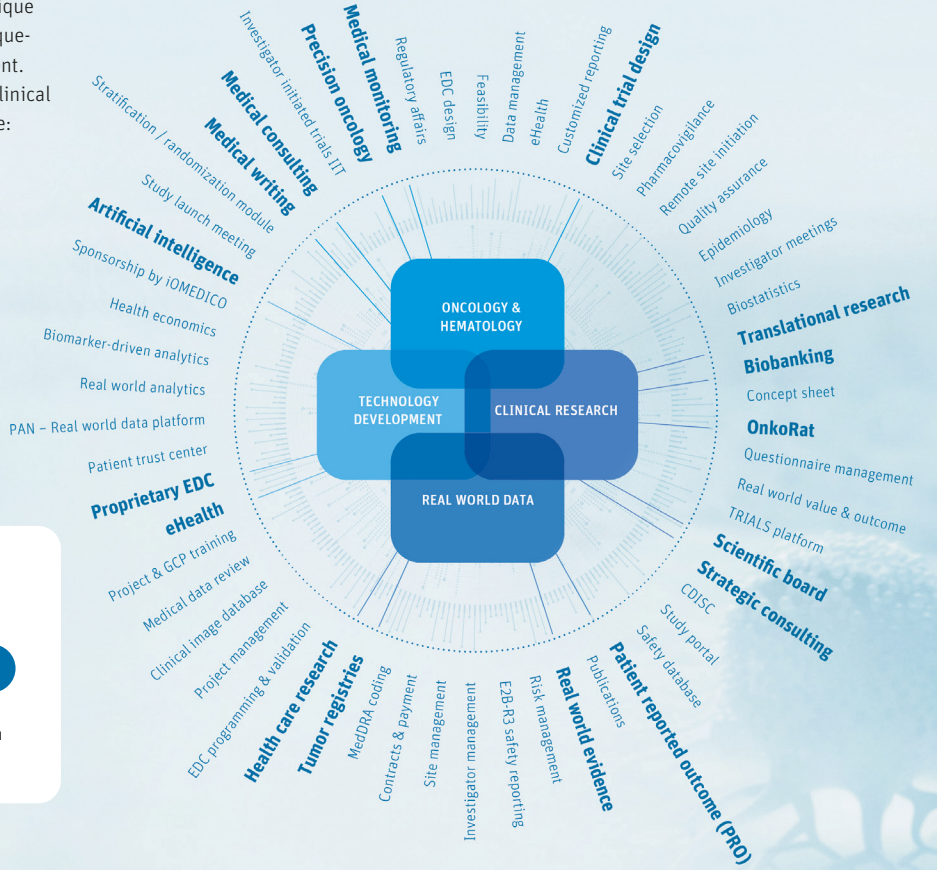
Data & Quality Metrics

>26.000 PRO data sets in our database

>230.000 questionnaires in the last 10 years

Excellent response rate: >75%

Our team of clinical oncologists and scientists care for each individual project. As a boutique CRO, we understand the uniqueness of your drug development. We offer you all services of clinical research from a single source: from design to publication.



Interested in working with us?

Contact us

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W: www.iomedico.com

Facts & Figures

Year of founding	1996
Head office	iOMEDICO AG, Freiburg i. Br., Germany
Management	Michael Pröschel, CEO Dr. med. Norbert Marschner, CSO Sybille Marschner, CHRO
Business segment	Clinical research organization and cancer research institute specialized in oncology and hematology, data-driven medicine and pharmaceutical development
Employees	> 130