PHARMALEX

REAL-WORLD EVIDENCE - UNIQUE POSSIBILITIES FOR REGISTER-BASED RESEARCH IN THE NORDIC COUNTRIES

In contrast to the controlled and homogeneous setting in RCTs, the real-world setting consists of a broader and more representative patient population, where treatments are not necessarily used in accordance to a strict protocol. Real-world evidence captures this complexity.

Real-world evidence is needed in many stages of a products' lifecycle; in the early phases of product development as well as to support a successful market access and uptake. There is an increasing demand for real-world evidence from health care providers and payers, not least from pricing and reimbursement authorities. Presenting real-world evidence can inform treatment and reimbursement decisions, and support a timely and successful product launch and access to market.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

Describe the natural course of the disease

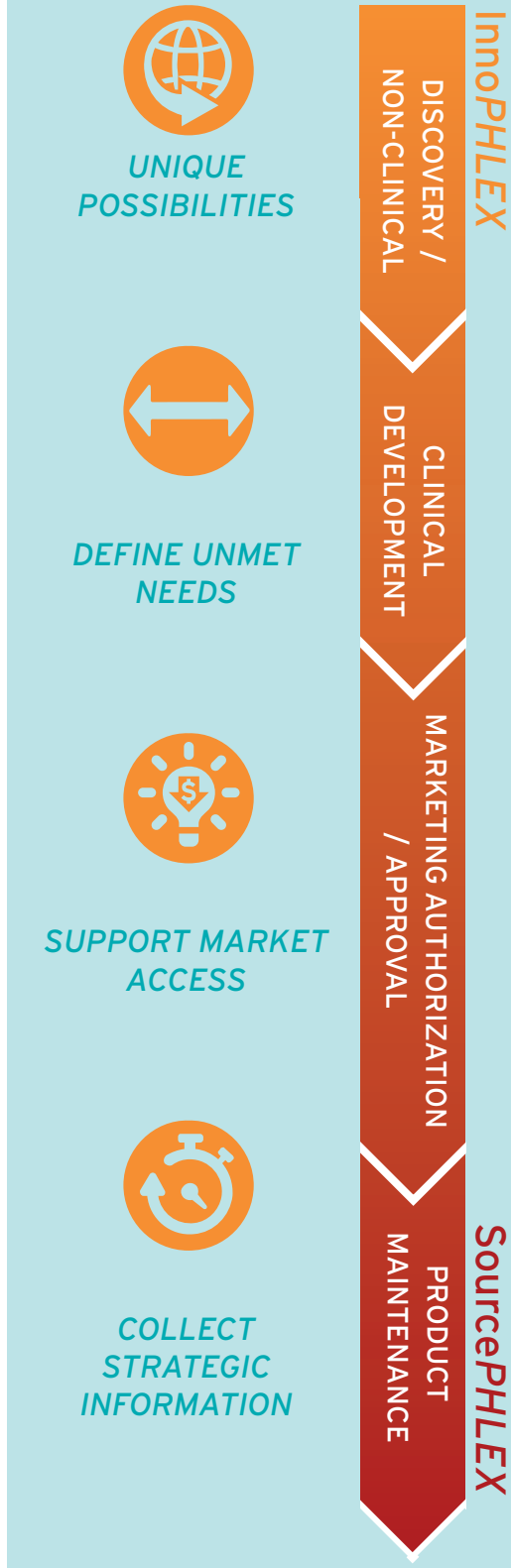
- Epidemiology of the disease (prevalence, incidence, etc.)
- Comorbidities
- Clinical pathways
- Progression and survival

Document the outcomes of current treatments in clinical practice

- Effects, e.g. clinical events and complications
- Treatment changes, e.g. change of doses, switches
- Tolerability

Support global health economic model development

- Describe how the disease is managed in clinical practice
- Demonstrate the costs of the disease to the health care sector and the society



DELIVERING SUCCESS WITH CONFIDENCE

CONTACT US

CAREN MARTINI
Senior Director
Head of Development Consulting
& Scientific Affairs
caren.martini@pharmalex.com

DR. MARTINA STEIPER
Senior Director, Principal Consultant
Development Consulting
& Regulatory Strategy
martina.steiper@pharmalex.com

"Since our founding in 1994, every single one of our clients is our top priority! We lead where others follow. We help clients to go beyond compliance, to capitalize on greater efficiencies, streamline complexity and to deliver true business value.

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Dr. Thomas Dobmeyer, CEO

PharmaLex is one of the largest specialized providers of **Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management** worldwide. Our global teams of experts can take you through early strategic planning activities and non-clinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

PharmaLex supplies the widest range of **highly-skilled leading experts**. Our experienced teams span **all geographies** to expedite product developments and provide **access to much needed resources**.

Stay **one step ahead** of essential requirements needed by health agencies worldwide. Our knowledge accelerates your business success...

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

850+
SUBJECT MATTER EXPERTS
WORLDWIDE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL
COMPANIES ARE
OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER
FDA AND EMA EXPERTS

50+%
OF OUR PROJECTS
ARE GLOBAL