## Legacy of Excellence in Real-World Evidence Generation at Arbor Research

### Who We Are

#### Historical Leaders in Real-World Evidence (RWE)

Launched the multinational Dialysis Outcomes and Practice Patterns Study (DOPPS) in 1996

ynamic and nimble non-profit with a nch track record of using causal inference principles to reduce bias in real-world data analysis

Experts in study design, site identification, and investigator engagement, with contract research organization (CRO) capabilities

## What We Offer

#### Support Throughout Clinical Development Life Cycle

Support randomized controlled trial (RCT) design and planning

Lead evidence generation and real-world effectiveness studies

#### Data Analysis

Proficiency in data curation, linkage, and management as well as biostatistics and epidemiology

#### **Data Solutions**

Access to and expertise with large public and private databases with opportunities for logistical/CRO support for custom prospective data collection

A unique global perspective to inform clinical practices, shape evidence-based guidelines and health policies worldwide, and ultimately improve patient outcomes

### **Data Generation and Access**

#### **Data Coordinating Center**

- 25+ years experience coordinating the international DOPPS, a cohort of >100K hemodialysis patients across 20 countries, as well as PDOPPS and CKDopps
- CRO capabilities in diverse international settings
- PARADIGM—a chronic kidney disease associated pruritus (CKD-aP) treatment registry to evaluate real-world outcomes of Difelikefalin in hemodialysis patient

#### Electronic Health Record (EHR) Extraction and Curation

- Modernized cost-efficient alternative to large cohort studies
- US dialysis: Long-standing relationships with multiple US dialysis providers and EHR data vendors with rich granular data on labs, medications, and clinical outcomes
- US CKD: Innovative partnership with NANI, a large nephrology practice with a robust database of >45,000 patients across 75 CKD clinics

#### **Public Data Sources**

- CMS claims: Includes Medicare-eligible patients in the US with and without CKD
- USRDS (United States Renal Data System): 300,000+ US dialysis patients with Medicare coverage
- Patient demographics, ICD-10 diagnoses and procedures, prescriptions, labs, hospitalizations, other dialysis related variables, and dialysis facility characteristics
- With years of United States Renal Data System leadership, Arbor Research has a unique understanding of this database tailored to dialysis

# **Contact Us**



Visit www.ArborResearch.org to learn more about how Arbor Research can serve your RWE needs

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### Transforming data into evidence: RWE across the spectrum of drug development

- **RCT planning**: Leverage observational data to clarify decision points and optimize design
- Evidence generation: Create a compelling case for unmet needs
- Post Authorization Safety Studies (PASS): Evaluate safety profiles for newly approved medications
- Real world effectiveness /registry: Understand medication utilization and performance in everyday clinical practice
- Monitoring trends: Stay up-to-date to understand management strategies and identify gaps in care
- External control arm: Identify active comparators embedded in a larger cohort study
- **Policy research**: Opportunities for natural experiments to understand the impact on practices and outcomes
- **Patient-reported outcomes (PROs)**: Pioneers in developing and capturing PROs to better understand the patient perspective

### **Research Output**

The Arbor Research RWE team has published hundreds of peer-reviewed manuscripts in scientific journals, including over 300 papers utilizing DOPPS data.

Deliverables can be defined flexibly dependening on the nature of the project, timeline of clinical development, and funder interests. Recent examples of output dissemination include:

- Manuscript or research letter publications in peer-reviewed journals
- Abstract publications and presentations at scientific conferences
- Internal-facing reports or dashboards with data and recommendations to support strategy
- Curated analysis-ready databases
- Document preparation for regulatory review
- Virtual (webinars and podcasts) and face-to-face (conference symposia) presentations targeted to health care professionals, patients, policy makers, and researchers



