

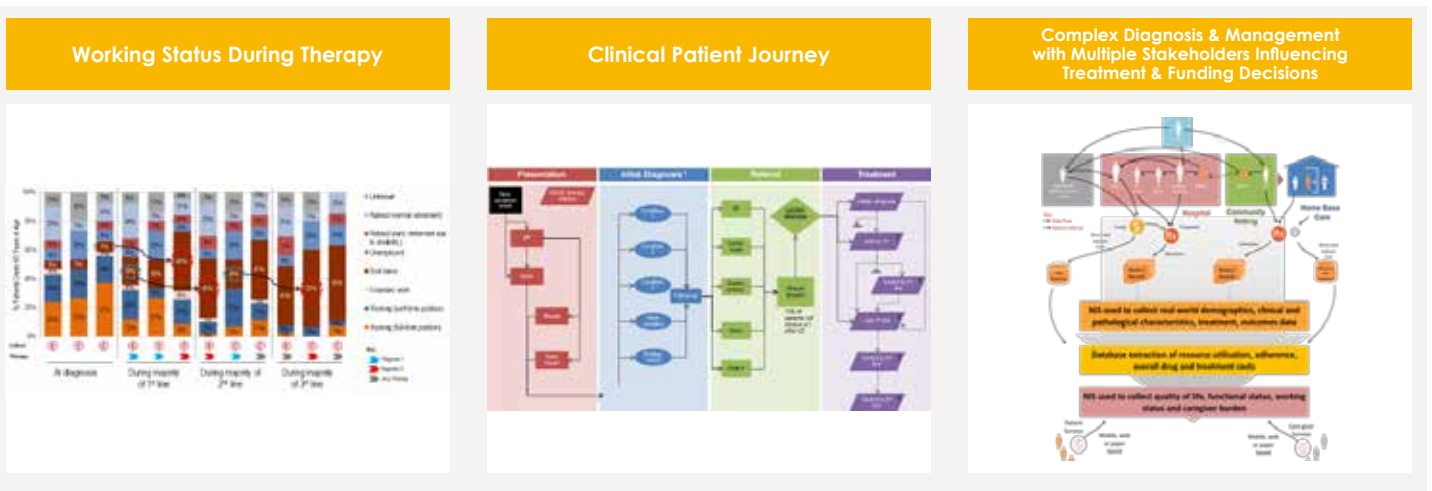
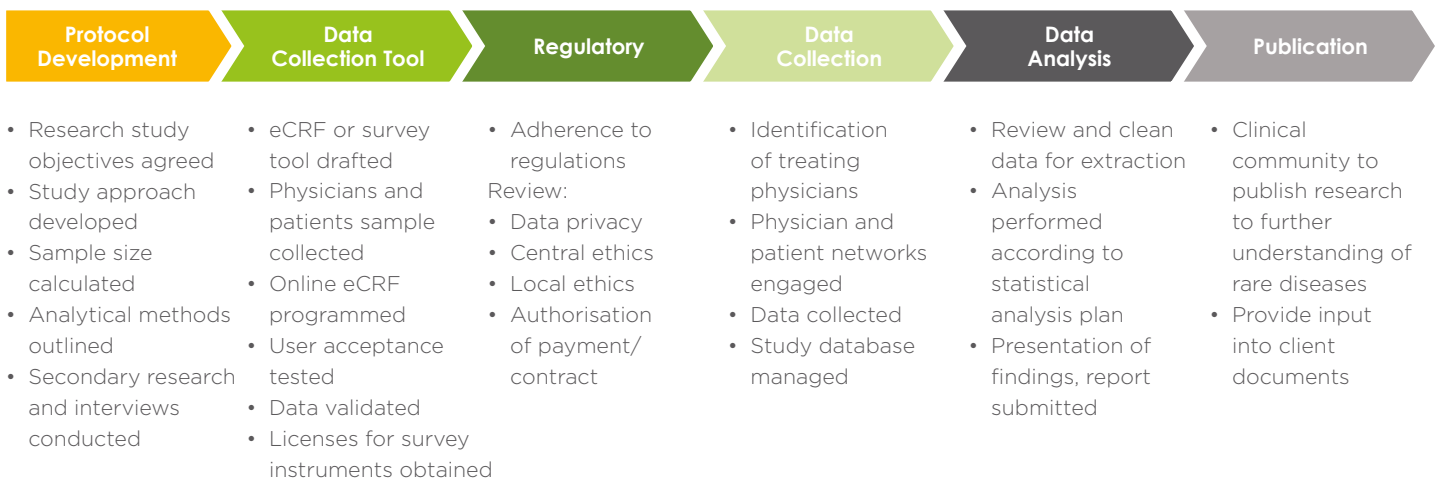
NON-INTERVENTIONAL STUDIES TO SUPPORT PAYER & CLINICAL DECISION MAKING: A RETROSPECTIVE CHART REVIEW

Global and local payer negotiations regarding funding and reimbursement of new drugs for rare diseases and specific subpopulations can be challenging, due to the lack of available real-world data. Traditional patient registries, if available, do not generally capture the level of detail required.

Data collection using retrospective chart review offers a faster and more flexible process for collecting robust real-world evidence. To ensure ongoing access, new therapies require further additional evidence to build a stronger clinical and economic case for long term treatment provision.

Navigant applies traditional and innovative methods for collecting real-world data through a combination of retrospective chart review, database extraction and patient survey methodologies.

NAVIGANT'S DATA COLLECTION MODEL PROCESS



A well designed and efficiently conducted retrospective chart review offers a fast, flexible and cost-saving alternative to a patient registry.

Outputs from the review include the history of rare disease, genotypic and phenotypic variability, plus differences in treatment patterns across countries and the clinical drivers of therapy use. This enables comparison of

real-world treatment practice versus clinical guidelines.

Collection of additional resources (visits, monitoring, additional therapies, etc) and institution-specific unit cost data, allows for calculation of overall direct costs to identify the impact treatment has on budget.

Data relating to patients and caregivers can be mapped on to medical chart data on

an individual patient basis, to define the burden of disease and provide patient perspectives on treatment outcomes.

Insights generated by implementing this methodology allow manufacturers to refine the product value proposition and provide the necessary evidence to support product access and reimbursement.

LIFE SCIENCES GLOBAL MARKET ACCESS CENTER OF EXCELLENCE:

ENVIRONMENT:

- Payer / stakeholder mapping
- Unmet needs & value driver assessment
- TPP Assessment & evidence requirements
- Payer funds flow / care re-design & pathway implementation
- Coding/Billing & Reimbursement Analysis

VALUE:

- Value Proposition Optimization
- Key Value Message Testing by stakeholder group
- Value story development
- Objection handling
- Roadmap for launch
- BD&L Assessments

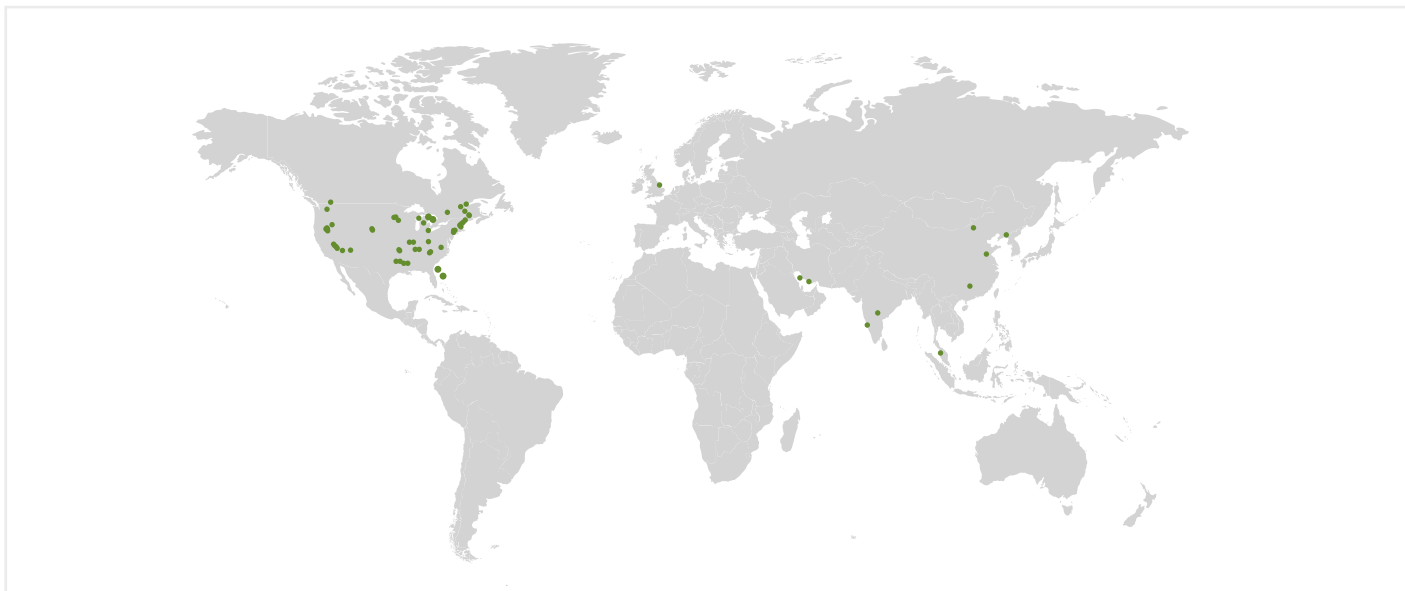
PRICING & REIMBURSEMENT:

- Qualitative Price Assessment
- Quantitative Price Finding & Access Studies
- Price build-up models
- Innovative pricing, contracting & managed entry agreements
- International Reference Pricing & Launch Sequence Modeling
- Mock Negotiations

EVIDENCE & Non-Interventional Studies:

- Clinical trial design & evidence requirements
- Retrospective Chart Reviews
- Pharmaco-epidemiological studies
- Patient / caregiver reported outcomes
- Registries
- Data mining

NAVIGANT'S GLOBAL OFFICES



- **Expertise in Pricing, Reimbursement & Access:** A dedicated global team with deep expertise in pricing, reimbursement and market access across product development and lifecycles
- **Global Network of Stakeholders:** Access to a broad range of stakeholders including national, regional and local payers, pharmacists, key opinion leaders (KOLs), physicians and patients
- **Rich Knowledge of Major Therapeutic areas:** Oncology, immunology, pain, cardiovascular, metabolics, antibiotics and vaccines
- **Rigorous Analysis to Deliver Tailored Actionable Insights:** Advanced analytics, innovative methodologies, and qualitative and quantitative research techniques designed to bring actionable insights
- **Industry Experience:** Extensive pharmaceuticals, biotech and medical devices experience in both commercial and clinical development
- **Global & Regional Perspectives:** We have the ability to deliver global, local and affiliate engagements through our global capabilities and resources

NAVIGANT'S LIFE SCIENCES EXPERTS

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