Real-World Data and Clinical Development

The road to approval is long, arduous, and costly.

Even the most robust Clinical Development Plans can encounter unavoidable roadblocks that deter timelines, results, and commercial expectations. Incorporating real-world data (RWD) can help refine strategy, optimize clinical trial designs, and efficiently demonstrate effectiveness and safety.

Let OM1's data and platforms guide you

As a tried and true data and technology partner, we leverage proprietary real-world datasets and reusable networks and platforms to accelerate execution of post-marketing commitments, feasibility studies, external control arms, pragmatic trials, natural history studies, and more.

Phase 1 | Phase 2 | Phase 3 | **Phase 4**

Phases 1-3

- **Market sizing:** Understand patient populations and treatment gaps for precision therapeutic targeting.
- **Protocol feasibility and site selection:** Optimize the real-world implementation of specific protocols based on an evaluation of eligibility criteria & impact on cohort size.
- **Patient Finder**: Confidently find the right patients for clinical trials; including patients with rare, undiagnosed, or misdiagnosed conditions, and subgroups by patient demographics.
- **External control arms**: Streamline your comparator by using RWD to eliminate trial enrollment and demonstrate efficacy.
- **Pragmatic trials and registries**: Fuel multiple clinical development initiatives, understand burden of disease and patient journeys, and gain access to voice of patient for study design.

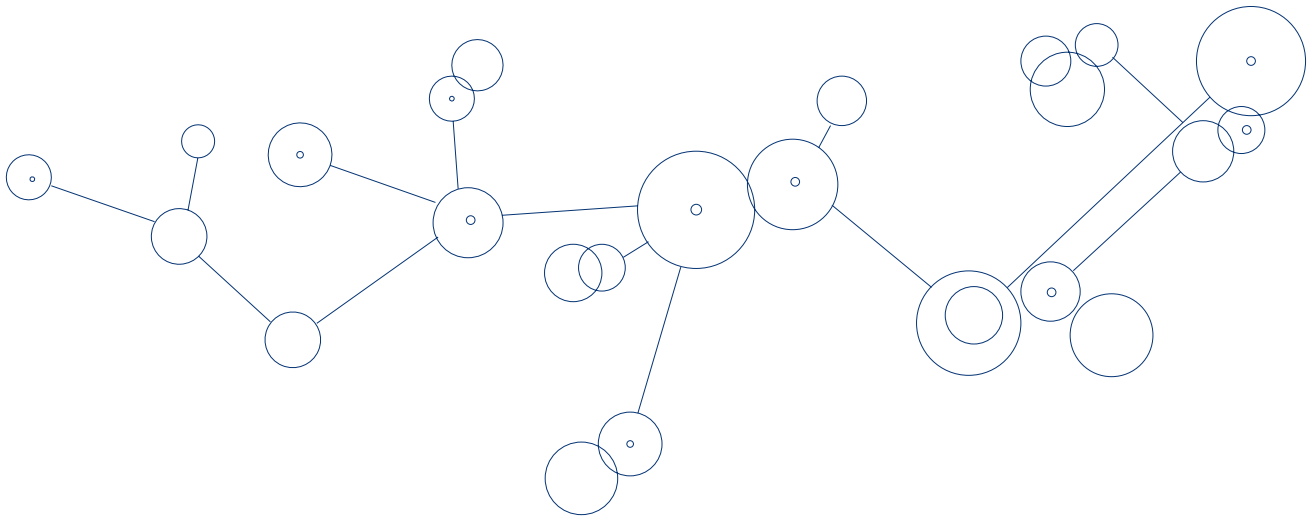
Phase 4 and Beyond

- **Safety surveillance**: Employ OM1's active data networks for population-based safety surveillance.
- **Post-marketing commitments**: Utilize OM1's evidence generation networks and automated registries to fulfill all your post-marketing needs, including safety, effectiveness, value, and off-label use.
- **Regulatory requirements**: Expand indication profile or use for part of regulatory approval with research-grade and regulatory-enabled RWD.

Why OM1?

- Longitudinal and multi-source networks in more than 8 therapeutic specialty areas
- Real-world data cloud based on billions of data points from more than 300 million patients
- Industry-leading and proprietary AI-generated models and technology for data extraction
- Proprietary EMR Engine technology that enables traceability and transparency needed for regulatory studies
- Strategic partnerships with specialty associations and their patient registries

Trusted by 9 of the top 10 pharma companies and 50% of the largest medical device companies



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