Insights and Lessons Learned From Implementing the Innovations in Genicular Outcomes Registry (IGOR): A Multicenter Prospective Registry of Knee Osteoarthritis

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OBJECTIVE

To share key lessons learned from designing and implementing the Innovations in Genicular Outcomes Registry (IGOR; NCT05495334), a prospective, multicenter, longitudinal, treatment-agnostic observational registry for participants with knee osteoarthritis (OA), to guide development of future real-world evidence registries.

CONCLUSIONS

1. IGOR has enrolled >4000 participants over 5 years, with enrollment ongoing, and has generated 8 peer-reviewed publications to date
2. Across the 5 operational domains of database architecture, site selection and training, patient recruitment/retention, operations, and documentation, the following recurring themes emerged:
   - Build flexibility into database design from inception to accommodate evolving clinical practice
   - Invest heavily in site education and continuous support and engagement to enhance data quality
   - Balance industry sponsorship with independent oversight to ensure transparency and scientific integrity while addressing cost barriers
   - Standardize documentation to clinical trial–level rigor
   - Proactively address participant access to technology and health literacy to enhance participation over extended follow-up periods
3. IGOR represents a model for how a well-governed, flexibly designed registry with strong sponsorship and rigorous data monitoring can generate high-quality, important real-world evidence that can ultimately inform clinical development and patient care
4. We hope these lessons can inspire development of real-world registries across other therapeutic areas

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INTRODUCTION

- Knee OA is a chronic condition that causes pain and functional limitations[1]; >15 million Americans have been estimated to have knee OA,[2] yet real-world data on the patient journey including patient-reported outcomes (PROs) for nonsurgical treatments remain limited
  - PROs are important tools to measure patient perception of the relative success of a clinical intervention[3]
- Patients with knee OA exhibit diverse clinical profiles that require tailored treatment pathways, with myriad treatment options, including nonpharmacologic approaches, topical and systemic therapies, local injection therapies, denervation therapies, and surgical interventions[4]
- Prospective clinical registries can bridge the gap between clinical trials, which do not usually reflect real-world practice and patient populations and thus lack generalizability, and retrospective chart reviews, which do not capture long-term treatment outcomes or the patient experience because PROs are not typically captured consistently[3,5]
- IGOR was developed as a prospective, multicenter, longitudinal, treatment-agnostic observational study to capture real-world clinical outcomes, including PROs and healthcare resource utilization data, across a broad spectrum of knee OA treatments, from medications through knee replacement[3]
- With >4000 participants enrolled over 5 years, ongoing enrollment, and 8 peer-reviewed publications to date, including a detailed description of the IGOR protocol (Table 1),[3] IGOR represents a model for medical condition–specific real-world evidence generation to capture the treatment journey of patients with knee OA and assist healthcare providers with practical clinical decision-making
- Designing and implementing IGOR required an extraordinary amount of planning and collaboration among healthcare providers, study site representatives, and the industry sponsor
- Herein, we share insights acquired and key lessons learned from the development of IGOR

Table 1. IGOR Publications

PMID	Title	Authors	Journal citation	doi
39691173	Innovations in Genicular Outcomes Registry (IGOR): protocol for a real-world registry study of treatments for knee osteoarthritis	Dasa V, Mihalko W, Rivadeneyra A, Urban J, Wickline A, Rogenmoser D, Concoff A, Spitzer A, Mont MA	*Ther Adv Musculoskelet Dis.* 2024;16:1759720X241304193	10.1177/1759720X241304193
40117656	Treatment journey for nonoperative symptomatic knee osteoarthritis: data from a new real-world registry	Spitzer AI, Mont MA, Lin JH, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, Ng MK, DiGiorgi M, Dysart S, Urban J, Mihalko WM	*Surg Technol Int.* 2025;45:sti45/1860	—
40092416	Association of knee osteoarthritis treatment types, patient characteristics, and medical history with subsequent risk for total knee arthroplasty: data from a new real-world registry	Concoff AL, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Ng MK, DiGiorgi M, Dysart S, Urban J, Mihalko WM, Mont MA	*Arthroplast Today.* 2025;32:101643	10.1016/j.artd.2025.101643
40104775	Improved sleep associated with triamcinolone acetonide extended-release injections for knee osteoarthritis: use of a new real-world registry	Mont MA, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, Ng MK, DiGiorgi M, Dysart S, Urban J, Mihalko WM	*Arthroplast Today.* 2025;32:101655	10.1016/j.artd.2025.101655
38942249	Cryoneurolysis associated with improved pain, function, and sleep in patients following total knee arthroplasty: use of a new real-world registry	Mont MA, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, Ng MK, DiGiorgi M, Dysart S, Urban J, Mihalko WM	*J Arthroplasty.* 2025;40(1):92-101.e3	10.1016/j.arth.2024.06.054
38936436	Improved pain and function with triamcinolone acetonide extended-release and cryoneurolysis for knee osteoarthritis: use of a new real-world registry	Mont MA, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, Ng MK, DiGiorgi M, Dysart S, Urban J, Mihalko WM	*J Arthroplasty.* 2025;40(2):328-338.e2	10.1016/j.arth.2024.06.055
42088071	Intraoperative liposomal bupivacaine is associated with reduced opioid use and enhanced recovery after total knee arthroplasty: a multicenter registry study	Ng MK, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, DiGiorgi M, Urban J, Mihalko WM, Mont MA	*Arthroplast Today.* 2026;39:101968	10.1016/j.artd.2026.101968
41093151	Preoperative cryoneurolysis improves pain and function for at least 12 months after total knee arthroplasty: a multicenter registry study	Ng MK, Lin JH, Spitzer AI, Dasa V, Rivadeneyra A, Rogenmoser D, Concoff AL, DiGiorgi M, Urban J, Mihalko WM, Mont MA	*J Arthroplasty.* 2026;41(6):1711-1719.e1	10.1016/j.arth.2025.10.011

KEY LESSONS LEARNED FROM IGOR

Across the 5 operational domains of database architecture, site selection and training, patient recruitment/retention, operations, and documentation, several recurring lessons emerged (Table 2).

Table 2. Key Challenges and Lessons Learned While Developing IGOR

Domain	Challenge	Recommendations and key insights
Database architecture	New treatments may not fit within existing database design (eg, peripheral nerve stimulation requires additional touchpoints for implantation, activation, and troubleshooting)	**Build flexibility into database design from inception; accommodate treatment landscape evolution with a structured review process**
	Database constraints can hinder long-term data capture as patient volume grows	**Design for scalability and longer follow-up from the outset; plan for finite database capacity with expansion mechanisms**
	Notifications sent at inconvenient times for certain time zones led to missed data entry windows	**Synchronize notifications to the local daytime of the recipient regardless of geographic location**
Site selection and training	Site qualifying visits are time intensive but essential; sites not screened adequately might not meet data capture requirements	**Conduct qualifying site visits; use a test site to identify enrollment time, follow-up burden, and database maintenance expectations before expanding**
	High staffing burden for smaller private or solo provider practices to meet data capture requirements	**Create an efficient infrastructure that facilitates easy data entry for clinical staff; balance site types (private vs institutional) to maximize data diversity**
	Site staff may lack clinical knowledge to distinguish similar procedures (eg, arthroscopy vs arthroplasty) or pharmacologic agents	**Provide standardized education guides (eg, Genicular Nerve Guide), pharmacy charts, and FAQ sheets; sponsor CRLs to onboard new staff rather than delegating to individual sites**
Patient recruitment/ retention	Electronic PRO collection requires participants to own and operate a personal electronic device, a barrier for some populations with knee OA	**Offer paper consent options; provide site access to devices or training; allow proxy data capture (up to 30% per protocol)**
	Extended follow-up (18 months per treatment) combined with high comorbidity burden in older participants increases dropout risk	**Provide reimbursement to patients for time to complete questionnaires to encourage adherence; conduct internal discussions to ensure prolonged follow-up does not overburden participants**
	Variations in health literacy and English proficiency among participants	**Develop content in languages other than English (eg, US Spanish) on the basis of demographic needs; consider dialects and cultural contexts (eg, proxy decision-making)**
Operations	High costs associated with registry maintenance, daily monitoring, and frequent participant follow-up	**Manage operations in-house with a hands-on team; use data and documentation options that ensure FDA compliance yet are cost effective; build database to minimize data management burden; focus on site education and collaboration**
	Challenges with participant access due to technical issues	**Involve a skilled technical team for rapid response; provide site and patient technical support; conduct frequent data backups**
Documentation	Vague/Evolving standards for registry documentation compared with clinical trials	**Create SOPs that mirror clinical trial standards to favor acceptance by regulatory bodies and policymakers to ensure long-term data integrity**
	Inconsistent data entry approaches across multiple study sites	**Deploy standardized tools such as EMR note templates; ensure consistent definitions of adverse events across all sites; provide ongoing standardized education to all sites (SIV, monitoring, correspondence, site sharing opportunities)**

CRL, clinical research liaison; EMR, electronic medical record; FAQ, frequently asked questions; FDA, US Food and Drug Administration; IGOR, Innovations in Genicular Outcomes Registry; OA, osteoarthritis; PRO, patient-reported outcome; SIV, site initiation visit; SOP, standard operating procedure.