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# Orthopedic Coordinated Registry Network (Ortho-CRN): advanced infrastructure for real-world evidence generation

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## BACKGROUND

Musculoskeletal conditions affect nearly three out of four persons aged 65 and older, one out of every two persons aged 18 and above and are responsible for up to one-third of pediatric medical problems.[1 2] The aging of the baby boomer generation, the increased demand for orthopedic procedures, and higher rates of osteoarthritis diagnoses have led to an exponential growth in orthopedic device-based procedures.[3–8] Total joint arthroplasty (TJA), one of the fastest-growing and most commonly performed surgeries, has a projected growth rate of 284% for total hip arthroplasty and 401% for total knee arthroplasty by 2040.[9–11]

The burden of treating musculoskeletal diseases has increased and accelerated medical product development. Each innovation shares a common goal, to repair, reconstruct, and replace musculoskeletal structures compromised by joint diseases, trauma, deformities, tumors, infections and painful orthopedic conditions in order to improve patients' physical function, self-image and ability to work. To meet the growing demand for the treatment of musculoskeletal conditions and ensure that orthopedic patients have access to high-quality, safe and effective medical devices, a different approach to support regulatory decision making is required. This article aims to summarize the role and next steps of the Orthopedic Coordinated Registry Network (Ortho-CRN) in the generation of real-world evidence (RWE) for the assessment and regulation of orthopedic devices.

### Key messages

⇒ There is a need to advance the medical device ecosystem and build a national infrastructure for faster, better and less costly evidence generation for orthopedic technologies.
⇒ The Orthopedic Coordinated Registry Network (Ortho-CRN) attempts to address gaps in clinical evidence to reliably capture real-world data for a range of orthopedic devices by promoting the development of systematic collaboration among existing national orthopedic registries, claims databases and other data sources.
⇒ Continuously addressing stakeholder needs, expanding the scope of the Ortho-CRN, amalgamating data sources and developing objective performance criteria is crucial for the generation of high-quality real-world evidence needed for the assessment of orthopedic devices.

### The role of real-world data and device regulation

For manufacturers to receive regulatory approval or clearance for a medical device, available evidence on the safety and effectiveness of orthopedic devices is assessed and based on non-clinical and clinical studies. However, clinical studies are often hindered by small sample sizes, limited follow-up and potential conflicts of interest among various stakeholders. In this complex environment, there is an increased need to advance the medical device ecosystem and build a national infrastructure to address the performance of orthopedic devices.[12] In some cases, real-world data (RWD) derived from sources outside of typical clinical trial settings, including electronic health records (EHRs), claims data, medical device and disease registries, patient-generated health data and data

gathered through personal devices and health applications, may be of sufficient quality to evaluate the safety and effectiveness of devices. RWD provides insight into the use and performance of the device in clinical practice, can capture a broader variety of patients, and can capture longer follow-up times if found to be fit-for-purpose. RWD can generate RWE to inform and support regulatory decisions, associated core research and surveillance infrastructure.[13] The evaluation of the performance of orthopedic devices using RWE can help make healthcare systems more efficient, aid in quality improvement and provide important evidence for decision-makers.[14]

CRNs play a pivotal role in developing high-quality evidence due to their ability to creatively organize real-world data collection systems, such as registries, that are relevant to the evaluation of medical devices, establish and grow the capacity of existing data sources, and leverage data sources that are created for other purposes such as documentation and billing for care.[15–17] The efficient capture of needed evidence makes CRNs a strong source of real-world data needed to evaluate the use of medical devices during clinical care.[18]

## DEVELOPMENT OF THE ORTHO-CRN

In September 2017, the Medical Device Epidemiology Network (MDEpiNet) launched the Ortho-CRN to build on the successes of the previously established International Consortium of Orthopedic Registries and promote the development of novel test methods, infrastructure and partnerships within the USA.[19] This collaboration of data partners and orthopedic community led to the creation of a CRN tasked with addressing the gaps related to orthopedic device evaluation across their total product life cycle. With the help of the MDEpiNet coordinating center, this organization leads the establishment of a broad infrastructure, through the systematic collaboration among existing national orthopedic registries, claims databases, and EHR data. The overarching objective of the Ortho-CRN is to promote the sharing of knowledge regarding best practices for data collection, linkages with other data systems, analytics, the dissemination of findings, and the development of innovative approaches for robust, relevant and reliable clinical evidence generation throughout the medical device total product lifecycle.[19]

These collaborations allow existing orthopedic registries to expand and further serve as high-quality data sources for comparative effectiveness research, aid in the generation of useful reports to health systems, conduct signal detection as well as implant tracking, and enhance the overall regulatory process through active surveillance. The Ortho-CRN is made possible by successful collaborations and partnerships among registries, regulatory agencies, and academic institutions.[20–24 25] All included registries (summarized in online supplemental appendix B) capture a variety of orthopedic procedures and include over 2 million patients and up to 17 years of follow-up data.

## ALIGNING STAKEHOLDER MOTIVATIONS TO LEVERAGE CURRENT ORTHOPEDIC REGISTRIES

To maximize the capabilities and applications of the Ortho-CRN, the needs and challenges faced by patient groups, clinicians, registry leaders, medical device manufacturers, medical device regulators and other stakeholders must be assessed and accounted for. From a patient's perspective, registries incorporated within the CRN provide an opportunity to capture outcomes that are meaningful to patients, including patient preference data and can be leveraged to support patients in numerous ways. This includes supporting patient engagement and education, aiding in the understanding of patient perspectives, in the identification of preferred areas for research prioritization, and assisting in shared decision making between patients and clinicians.[26] Within the clinical community, the focus is primarily on the value of registries in relation to quality performance measurement and reporting, as well as documentation of the efficiency of care. The ability of registries to provide actionable feedback to clinicians regarding quality-of-care metrics, performance benchmarks and patient outcomes is crucial. Challenges identified by clinicians, researchers, and registry leaders are primarily related to data collection and curation, including preservation of patient privacy, the associated time, cost, personnel, and accuracy issues associated with data collection.[27]

Medical device industry representatives identified the potential benefits and cost saving of a single source of data available to all companies, as this avoids the need for dual data entry by leveraging an existing network of data sources.[28] These data could be used for postmarket device surveillance when postmarket data collection is required by Food and Drug Administration (FDA) or other regulatory authorities. Registries can also supplement an existing company's claims data to increase long-term follow-up, capture additional outcomes including radiographic imaging, support clinical trial designs and mitigate shortcomings and biases inherent in retrospective data collection. The economic benefits of leveraging existing registries rather than creating new registries or conducting clinical trials were acknowledged. Registries are also a potential source for additional evidence required for the expansion of indications and can become a source of controls for new device trials. From a regulatory viewpoint, major goals related to the Ortho-CRN include the development of a framework to allow US orthopedic device registries to conduct signal detection and confirmatory studies using existing US registry data; to collaborate with international registries to investigate device signals and conduct comparative effectiveness research; to provide a platform for collaborative post-market surveillance of implants in the USA; and to facilitate tracking of implants and optimize premarket regulatory processes.[29 30]

## MOVING FORWARD: AREAS OF EXPANSION

The registries currently included within the Ortho-CRN primarily capture data related to hip and knee arthroplasty procedures. Stakeholders recognize that additional opportunities exist across multiple orthopedic device areas for the detection of safety events and evaluation of clinical effectiveness for currently marketed medical devices. Specific subspecialty areas that could benefit from the expansion of the Ortho-CRN include pediatric and adult spinal disorders, shoulder disorders, foot and ankle disorders, trauma and osseointegrated prostheses. Registries are an ideal method for postmarket evaluation among these aforementioned clinical spaces given that patients are treated with a relatively new class of orthopedic implants used with increasing frequency, are implanted in small heterogeneous populations, require long-term follow-up during critical phases of growth and development, experience concomitant use of combination products including biologics, and experience adverse events and outcomes that may be device and clinical are specific such as local infections and osseous union.

## MOVING FORWARD: METHODOLOGICAL ADVANCEMENTS TO STRENGTHEN THE GENERATED RWE

Identified methodological advancements that promote the objective of the Ortho-CRN for the development of innovative approaches for robust, relevant and reliable clinical evidence generation throughout the medical device total product lifecycle include data linkages and the generation of objective performance criteria (OPC).

Data linkages are especially crucial for postapproval safety evaluations of orthopedic devices, where important outcomes often do not occur until many years following implantation. Data linkage between registries and claims data may present a potentially cost-effective option for the evaluation of a device's total product life cycle and overcome the limitations of the respective data sources. Registries are limited in their capture of long-term follow-up data and capture of events or diagnoses that are not directly reported to the registry or occur outside the registry's health system. Meanwhile, claims data capture care received in various settings and provide more long-term information regarding experienced outcomes.[17] The MDEpiNet's coordinating center has initiated the data linkage process that allows for a more comprehensive assessment of orthopedic devices. More specifically, the center has previously successfully linked registry participants within the American Joint Replacement Registry to New York State claims data captured by the Statewide Planning and Research Cooperative System.[31]

OPC refer to a numerical target value derived from historical data.[13 32] Technologies, such as orthopedic devices that undergo incremental but important changes, may greatly benefit from OPC creation. The creation of OPCs may allow for comparison of important outcomes, such as revision rates, at specific time points to a defined standard or equivalent standards, which can be used as a comparison for devices seeking approval.[33] From a regulatory premarket standpoint, leveraging OPCs may reduce the sample size requirements for studies, be cost-effective, and may promote the use of RWE if appropriately developed, applied, and disseminated. For postmarket surveillance, OPCs allow for the examination of the impact of incremental innovations in implant characteristics. There are some legacy benchmarks developed for certain orthopedic device types, however, there is still a need to advance the methodology for the creation of OPC.[34–37]

## RESEARCH NEEDS: DISPARITIES IN ORTHOPEDIC PROCEDURAL OUTCOMES

Sex differences in the prevalence of common indications for orthopedic devices exist.[38 39] A higher proportion of women undergo TJA and experience unfavorable outcomes following TJA.[38 39] Furthermore, it is known that sex is associated with varying effectiveness and safety profiles among medical devices.[40] For these reasons, the FDA released specific guidance regarding the investigation of sex differences among patients receiving medical devices, and the FDA Center for Devices and Radiological Health (CDRH) initiated efforts to increase women's access to safe medical devices through the CDRH Health of Women Strategic Plan.[41] Racial disparities have also been identified within orthopedic procedures and outcomes.[42] Racial and ethnic disparities for joint arthroplasty outcomes in the USA have been well documented in literature and may, at times, also result in conflicting evidence.[43–46] Additionally, strong and growing evidence demonstrates that social determinants of health (SDoH), defined as the structural determinants and conditions in which people are born, raised, reside, work and age, often predict healthcare access, health status, utilization of healthcare, and health outcomes.[47 48]

Further investigation into sex, gender, racial disparities, and SDoH will help clinicians and regulators gain an understanding of the effects of utilization and can serve as a decision aid in selecting treatment.

## CONCLUSIONS

The Ortho-CRN and its overarching objectives are crucial to ensure advancements related to infrastructure building, regulatory investigations, and quality improvement across a range of orthopedic device areas. Continuously growing the capacity of the Ortho-CRN may contribute to the enhancement the data, advancement of methodologies, and aid in the goal of near-real-time access to RWD that can be used for active safety surveillance. As a member of the CRN Collaborative Learning Communities, Ortho-CRN is well positioned to continue to build a strong foundation and promote the efforts of the National Evaluation System for health Technology in the registry-based domain.

## APPENDICES

**Appendix A. Ortho-CRN 2018 and 2019 Annual Meeting Speaker List**

| First name | Last name | Affiliation/Organisation |
|---|---|---|
| Elizabeth | Adegboyega-Pa nox | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| Vinicius | Antao | Hospital for Special Surgery |
| Philip | Belmont | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| John | Braun | Massachusetts General Hospital |
| Patrick | Cahill | Children's Hospital of Philadelphia |
| Terri | Cornelison | FDA/CDRH |
| Jack | Cronenwett | Vascular Quality Initiative |
| Vincent | Devlin | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| Jeffrey | Dunkel | Titan Spine |
| Tara | Federici | AdvaMed |
| Patricia | Franklin | UMass Medical School/Northwestern |
| Jonathan | Forsberg | Department of Defence |
| David | Gebben | FDA/CDRH/OST |
| Stephen | Graves | Australian Orthopaedic Association National Joint Replacement Registry |
| Daniel | Guss | American Orthopaedic Foot & Ankle Society |
| Brian | Hallstrom | Michigan Arthroplasty Registry Collaborative Quality Initiative |
| Richard | Hughes | Michigan Arthroplasty Registry Collaborative Quality Initiative |
| Said | Ibrahim | Weill-Cornell Medicine |
| Noelle | Larson | Mayo Clinic |
| Nilsa | Loyo-Berrios | FDA/CDRH/Office of Clinical Evidence and Analysis |
| William | Maisel | FDA/CDRH/Office of Product Evaluation and Quality |
| Jialin | Mao | Weill-Cornell Medicine |
| Danica | Marinac-Dabic | FDA/CDRH/Office of Clinical Evidence and Analysis |
| Michelle | Marks | Harms Registry/ Setting Scoliosis Straight |
| Michael | Medina | Zimmer |
| Mark | Melkerson | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| Paul | Mraz | ApiFix Ltd. |
| Ronald | Navarro | Kaiser Permanente |
| Peter | Newton | Rady Children's Hospital/ Harms Registry |
| Gregory | Pappas | FDA/CBER |
| Elizabeth | Paxton | Kaiser Permanente |
| Raquel | Peat | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| Terrie | Reed | FDA/CDRH/OST |
| Kristina | Rosinia | American Academy of Orthopaedic Surgeons |
| Amer | Samdani | Shriners Hospital for Children |
| Art | Sedrakyan | Weill-Cornell Medicine |
| William | Shaffer | American Academy of Orthopaedic Surgeons |
| Richard | Skolasky | Johns Hopkins Spine Outcomes Research Centre |
| Brian | Snyder | Harvard |
| Paul | Tornetta | Boston Medical Centre |
| Michael | Vitale | Columbia |
| Paul | Voorhorst | Johnson & Johnson |
| Stephen | Weber | FDA/CDRH/Office of Orthopaedic Devices (OHT6) |
| Robbert | Zusterzeel | FDA/CDER, NEST Coordinating Centre |

**Appendix B. National and International Registries comprising the Ortho-CRN**

| | |
|---|---|
| Kaiser Permanente's Total Joint Replacement Registry (TJRR)[20 21] | The Kaiser permanente implant registries were developed in 2001 and modeled after the swedish Hip registry. kaiser permanente has several inter-regional implant registries that capture patient demographics, implant characteristics, surgical techniques, and outcomes, including a variety of orthopedic devices/surgeries such as total knee/hip, anterior cruciate ligament, spine, shoulder, and hip fracture. The device registries were developed to address recall situations, disseminate best practices, identify patients at risk for failure, and assess the clinical effectiveness of total joint replacement implants. The overarching goal of the registry is to enhancing quality and patient care. In addition to the inter-regional implant registries, Kaiser Permanente also has the world's largest private-sector electronic health records, Kaiser Permanente HealthConnect®. Interconnection of all patient encounters within the electronic health records allows for the extraction of laboratory, procedural, diagnostic, pharmacy, and hospital encounters for all members in every patient care setting across Kaiser Permanente's regions. These data supplement inter-regional implant registries and provide a foundation for longitudinal assessment of medical devices. |
| Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI)[24] | MARCQI started in 2012 as a major statewide quality improvement initiative to improve the care of hip and knee joint replacement surgery procedures. Since 2012, more than 70,000 hip replacements and over 130,000 knee replacements have been included and almost all hospitals and surgeons in Michigan participate in the registry. The registry captures 224 data elements, patient reported outcomes, procedure-related outcomes within 90-days, and revisions indefinitely. The registry is funded by Blue Cross and Blue Shield of Michigan and Blue Care Network, which enables a longitudinal assessment of revisions and other endpoints. MARCQI produces annual reports summarizing device-specific revision risks calculated from longitudinal assessments. |
| Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR)[22] | FORCE-TJR registry, created and managed by University of Massachusetts Medical School's Department of Orthopedics, collects, and analyzes comprehensive post-TJR data on more than 24,000 patients treated by a diverse and representative group of surgeons and hospitals in 24 states (urban and rural, academic and community hospitals, low and high-volume practices) to date. Patient enrollment is ongoing and exceeded 35,000 in 2015. Uniquely, patients consent to (a) complete annual patient-reported outcomes (pain and function) and (b) report adverse events and surgical revisions at intervals for years into the future. A secure web-based data collection platform is used for direct data submission from patients and clinicians. Longitudinal data is complete with at least 85% follow-up for patient-reported outcomes. |
| International Consortium of Orthopedic Registries (ICOR)[25] | ICOR captures over 5.2 million implants from 30 registries within 14 countries. This makes ICOR one of the largest collaborations between stakeholders with research and clinical expertise. These collaborations facilitate and enhance inter-registry collaboration to set up the infrastructure for a worldwide implant database. The developed infrastructure will promote international comparative effectiveness and device safety studies. |

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