

OrthoCompass · PROPELLER

ANZ evidence infrastructure for global musculoskeletal portfolios.
Prospective · HREC-approved · Independently administered · IMDRF-aligned

Corey Scholes
cscholes@ebma.com.au · 0421 160 417
119 Willoughby Rd, Willoughby NSW

EU MDR Article 61 and evolving PMCF requirements are driving demand for prospective, independently administered real-world evidence across all markets. **Australia is one of the highest-quality RWE jurisdictions available to a global musculoskeletal portfolio** — and it is systematically under-utilised. OrthoCompass–PROPELLER is the evidence infrastructure that changes that.

© THE ANZ MARKET

English-language. IMDRF founding member. High surgical volume relative to population. Independent regulator. Globally portable data standards. A uniquely legible RWE source for FDA, EMA, and TGA submissions alike.

≡ PROPELLER REGISTRY

Patient Reported Outcomes for Professional Education, Learning and Research. A pseudonymised, prospective national registry aggregating procedure-level musculoskeletal outcomes across Australia. HREC-approved. Independent.

○ EBM ANALYTICS

The service layer. Daily list processing, active chart review, patient contact, data quality assurance, and program reporting — removing the administrative burden from participating surgeons entirely.

WHY AUSTRALIA FOR RWE

Australia combines features that are rare in a single market: a large, geographically concentrated surgical community operating in English, under an independent regulator (TGA) that is a founding IMDRF member, with well-established data infrastructure and no language or coding barrier to international evidence transfer.

Surgical volumes are high relative to population — Australia performs approximately **55,000 knee replacements and 25,000 hip replacements annually**, with comparable per-capita rates to the US and EU. For non-arthroplasty procedures, volumes are proportionally higher still.

GLOBAL PORTABILITY

Data collected under PROPELLER’s framework meets the evidentiary standards recognised by the TGA, and is directly relevant to regulatory submissions to FDA, EMA, Health Canada, and PMDA under the IMDRF’s harmonised RWE guidance. New Zealand participation is available as an extension of the same program.

THE PMCF OBLIGATION

EU MDR Article 61 requires manufacturers of Class IIb and III devices to conduct ongoing post-market clinical follow-up — prospective, structured, and documented. Notified Bodies are increasingly scrutinising PMCF plans that rely on literature review alone.

PROPELLER generates the prospective, independently administered, procedure-level outcomes data that satisfies PMCF requirements — across indications the AOANJRR was never designed to capture.

TGA · FDA ALIGNMENT

As a founding IMDRF member, the TGA operates within the same harmonised framework as the FDA, Health Canada, and PMDA. The TGA’s own RWE guidance recognises independently administered registries as high-quality post-market evidence capable of demonstrating compliance with Essential Principles.

THE EVIDENCE GAP

The AOANJRR — Australia’s national arthroplasty registry — is a revision-rate surveillance system. It captures implant longevity. It was never designed to capture the full clinical picture your evidence team needs:

- ✗ Non-arthroplasty procedure outcomes (ligament, rotator cuff, fracture fixation)
- ✗ Patient-reported function, pain, and quality of life at any stage
- ✗ Complications and adverse events below revision threshold
- ✗ Procedure-level benchmarking across indications
- ✓ **PROPELLER captures all of the above.**

WHAT YOUR EVIDENCE TEAM RECEIVES

De-identified, aggregated program outputs structured for PMCF documentation and post-market surveillance use.

Prospective PROMs and complication data across all procedures your devices are used in - not just arthroplasty.

Active signal detection - adverse events identified through chart review, not passive reporting.

Quarterly program reporting on recruitment, data completeness, and cohort characteristics.

Auditable governance record - HREC-approved, pseudonymised, arm’s-length administration.

PROPELLER vs AOANJRR	OrthoCompass · PROPELLER	AOANJRR
Non-arthroplasty procedures	✓ All musculoskeletal except spine	✗ Not captured
Patient-reported outcomes	✓ Core data collection	✗ Not collected
Sub-revision adverse outcomes	✓ Active chart review	✗ Not captured
Arthroplasty implant tracking	Complementary	✓ Primary purpose
Real-time data access	✓ On demand	Annual reports only
Independent administration	✓ EBM Analytics	✓ AOA

~80k joint arthroplasty p.a.	~3x Non-arthroplasty procedures p.a.	IMDRF founding member · TGA	HREC ethics approved · pseudonymised	NZ+ extension available on request
DATA GOVERNANCE Sponsors receive de-identified, aggregated outputs only. No individual patient or surgeon data is shared.	ETHICS (HREC) Equivalent to US IRB approval. Program operates under independent HREC oversight.	ARM’S-LENGTH ADMIN EBM Analytics controls methodology and outputs independently. Sponsor does not direct data collection.	EXIT TERMS 60 days’ written notice. No penalties. Participants may continue on a self-funded basis.	PMCF DOCUMENTATION Program outputs are structured for inclusion in PMCF reports and PMS dossiers.