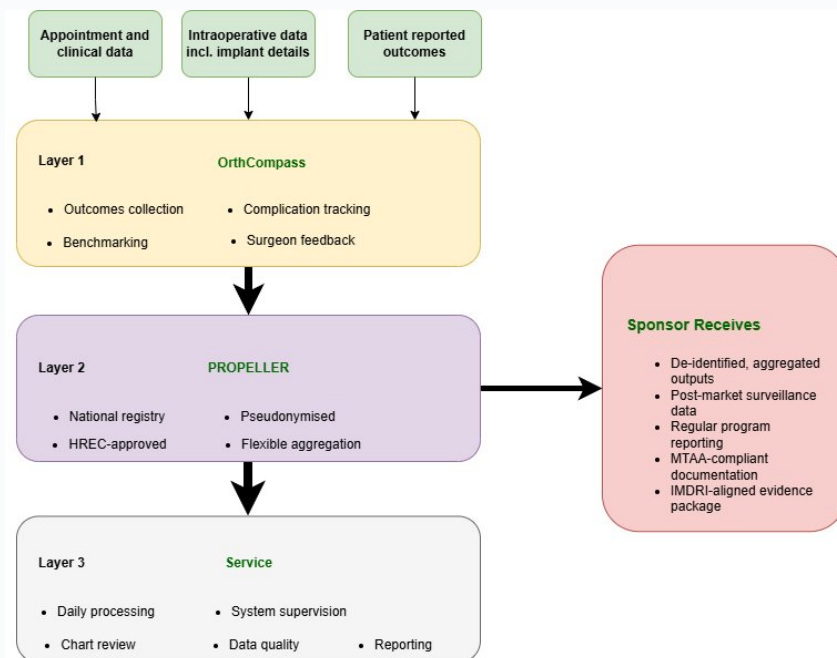


OrthoCompass + PROPELLER

Evidence-generating infrastructure for the Australian orthopaedic community.
Prospective · Independently administered · HREC-approved · MTAA-compliant

The AOANJRR captures revision rates. It was never designed to capture what happens to patients who don't reach revision or for the full range of procedures your devices support. **PROPELLER does**. Sponsoring surgeon participation builds an independent, structured evidence pipeline across every procedure your devices are used in.

HOW IT WORKS



WHAT THE AOANJRR CANNOT TELL YOU

- ✗ Non-arthroplasty patient recovery (rotator cuff, ligament, fracture)
- ✗ Complications that don't reach revision threshold
- ✗ Patient-reported function, pain and quality of life
- ✗ Procedure-level outcomes beyond arthroplasty

✓ **PROPELLER captures all of the above.**

REAL-WORLD EVIDENCE

For non-arthroplasty procedures, PROPELLER is the only structured RWE pipeline in Australia at this level of procedural granularity — PROMs, complications, and clinical outcomes across indications no existing national registry captures.

A national ACL registry has been piloted and publicly advocated. If established, it will not capture complications below revision, procedure-level benchmarking, or the broader musculoskeletal scope PROPELLER covers — and it is not operational today.

REGULATORY DIRECTION OF TRAVEL

From **21 March 2026**, facilities must report Class III device adverse events directly to the TGA. Active TGA reforms signal formalised post-market clinical follow-up (PMCF) requirements ahead - aligned with IMDRF guidance and the EU MDR trajectory.

TGA RECOGNITION

The TGA's RWE guidance recognises prospective, independently administered registries as high-quality post-market evidence capable of demonstrating compliance with Essential Principles. PROPELLER meets that description.

MTAA-COMPLIANT ENGAGEMENT

Sponsoring participation is not a workaround - it is the **correct mechanism**. Your compliance function needs three things:

Independent selection. EBM Analytics selects against agreed objective criteria. Sponsors cannot nominate individuals.

Documented purpose. The Agreement records legitimate purpose and prohibition on promotional intent, satisfying MTAA Code requirements.

Arm's-length administration. EBM Analytics controls methodology and outputs independently.

COMMERCIAL FLEXIBILITY

- **Build groups of surgeons sharing a clinical interest instantly** — ligament, shoulder, fracture, or any cohort - within one Sponsor Agreement.
- **Adjust scope** as products launch or indications expand.
- **Outputs segmented by Special Interest Group** - relevant data per team, without combining unrelated cohorts.

WHAT SPONSORS RECEIVE

De-identified, aggregated program outputs structured for post-market surveillance. No individual patient or surgeon data.

Auditable MTAA compliance record — documented legitimate purpose, independent selection, arm's-length administration.

Quarterly reporting on recruitment, PROM completion, and data quality.

GLOBAL UTILITY · IMDRF ALIGNMENT

Independently administered ANZ registry data is a material upstream asset for global medical affairs and regulatory teams.

WHAT SPONSORS SEE

De-identified, aggregated outputs only. No individual patient or surgeon data is ever shared.

PARTICIPANT SELECTION

EBM Analytics selects independently based on agreed criteria.

CLINICAL INDEPENDENCE

Nothing in the Sponsor Agreement affects a participant's independent clinical judgment.

GOVERNANCE

HREC-approved. Pseudonymised. Three-party agreement: Sponsor · EBM Analytics · Participant.