

Clinical Evidence: Building Confidence in Adoption



For musculoskeletal devices, clinical evidence helps explain who benefits, what outcomes to expect and why clinicians should consider changing practice.



Start with the decision

DEFINE THE INTENDED USE

Be clear about the patients, indication and claims the device is intended to support.

PLAN FOR ADOPTION

Align regulatory needs with the questions surgeons and hospitals will ask. Permission to market does not establish superiority.



Measure meaningful benefit

PATIENT OUTCOMES

Assess pain, function, mobility and quality of life using measures suited to the condition.

LOOK BEYOND IMAGING

Healing, fusion and tissue integration may matter, but do not automatically prove better outcomes for patients.



Make the evidence credible

RELEVANT COMPARISONS

Where comparison is needed, study the treatment the device would actually replace.

DESIGN BEFORE RECRUITMENT

Justify sample size and analysis. Address patient selection, surgical technique and rehabilitation to reduce bias.



Follow through over time

SAFETY AND DURABILITY

Match follow-up to the claims and risks. Record complications, reinterventions and missing data.

KEEP LEARNING AFTER LAUNCH

Use suitable post-market studies and registries to assess broader use. Report limitations and update the evidence plan.

Build the evidence behind your claims

Plan clinical, regulatory and commercial needs together. Generate evidence relevant to the intended patients, claims and decisions, then strengthen it throughout the product's life.

Sources: FDA pivotal clinical investigation guidance (2013); FDA PRO guidance (2022); MDCG 2020-7.

Flexible, on-demand commercial support

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