



CLINICAL & PROFESSIONAL RESOURCES

Clinical Pilot Planning Guide

A pre-enrollment planning framework for clinical question selection, regulatory and IRB determination, protocol development, site readiness, monitoring, and responsible decision-making.

Designed for
Clinical, research, biostatistics, regulatory, compliance, IRB,
rehabilitation, data, quality, and health-system leaders.



Regulatory status

FDA 510(k) pending. ISO Metrik has not received FDA clearance for the proposed clinical uses described in this resource. This document is for professional education and pathway planning; it is not authorization to market, ship, prescribe, bill, or use an investigational device.

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A pilot must evaluate the pathway and satisfy the applicable investigation requirements

A pilot can examine patient identification, clinician readiness, workflow, treatment feasibility, safety, adherence, outcomes, referral coordination, data quality, and implementation barriers. Calling an activity a pilot does not bypass FDA device-investigation or human-subject protection requirements.

510(k) pending ISO Metrik has not received FDA clearance for the proposed clinical uses described in this guide. A pending submission is not marketing authorization.	Pre-enrollment determination Before participant activity, the sponsor and reviewing institution determine whether the activity is research and whether the device investigation is significant risk, nonsignificant risk, or exempt.
Required approvals Significant-risk studies require an FDA-approved IDE and IRB approval before initiation. Nonsignificant-risk studies require IRB approval and abbreviated IDE compliance.	Controlled investigation Informed consent, investigational labeling, monitoring, records, reports, device accountability, privacy, and institutional requirements apply as appropriate.
No implied authorization	A website inquiry, planning call, protocol draft, site interest, device request, or pending 510(k) does not authorize participant enrollment, shipment, investigational use, promotion, commercialization, or a representation that the device is safe or effective.

Questions the organization should be prepared to answer

Patient identification Can service lines recognize and refer a defined population using supportable eligibility criteria?	Clinician readiness Can participating therapists complete the required training, demonstrate competency, and apply the protocol consistently?
Treatment feasibility Are fit, dosage, visit flow, home practice, documentation, and reassessment practical for clinicians and participants?	Safety and tolerance Which symptoms, tissue responses, deviations, modifications, discontinuations, and adverse events will be captured and escalated?
Outcome capture Can the team collect relevant impairment, function, participation, patient-reported, adherence, and implementation measures?	Decision value Which predefined result would lead the organization to refine, expand, formally study, pause, or stop the pathway?

Core stakeholders

- Clinical sponsor and relevant medical service-line champions.
- PT, SLP, rehabilitation leadership, participating clinicians, and outpatient operations.
- Research, biostatistics, regulatory, compliance, legal, privacy, and IRB representatives.
- Data management, quality, safety monitoring, patient education, and device accountability teams.
- Executive sponsor and the decision-maker responsible for implementation after the study.

Six controlled phases

01	Define the use case Select the population, care setting, research or quality question, pathway owner, hypothesis, and decision the pilot must inform.
02	Determine regulatory and study status Document whether the activity is research and whether the device investigation is significant risk, nonsignificant risk, or exempt, with sponsor, IRB, FDA, and institutional input as applicable.
03	Build the protocol Specify eligibility, intervention, comparator if any, training, measures, sample-size rationale, safety, consent, data handling, oversight, monitoring, and analysis.
04	Prepare sites and clinicians Complete approvals, execute agreements, train the team, verify competency, control device inventory, rehearse documentation, and test referral flow.
05	Enroll, treat, and monitor after approval Begin participant activity only after required approvals are in place, then use prospective tracking, safety review, protocol-fidelity checks, privacy controls, and device accountability.
06	Analyze, report, and decide Report results and limitations, preserve the study record, communicate required safety information, and apply the predefined decision criteria.

Protocol and governance checklist

Population and eligibility Diagnosis, timing, medical stability, precautions, exclusions, referral source, consent capacity, and screening documentation.	Intervention definition Device version, orientation, mode, resistance, dosage, visit schedule, home practice, co-interventions, allowed modifications, and stopping rules.
Training and fidelity Role-based curriculum, nine-module completion, assessments, practical sign-off, protocol training, fidelity checks, deviations, and retraining.	Safety oversight Expected responses, adverse-event definitions, clinical escalation, unanticipated problem review, device complaints, reporting timelines, and stopping rules.
Data and analysis Measures, time points, source documents, missing-data plan, privacy, access, quality checks, sample-size rationale, analysis, and publication plan.	Device control Investigational labeling, shipment authorization, receipt, inventory, storage, dispensing, return, reconciliation, maintenance, and disposition.

Outcome framework

Safety and feasibility Eligibility yield, training completion, tolerance, deviations, adverse events, retention, and data completeness.	Clinical response Diagnosis-appropriate facial, oral-motor, speech, swallowing, functional, and patient-reported measures.
Participant experience Usability, confidence, burden, home adherence, understanding, and relevance to personal goals.	System performance Referral completion, access, visit workflow, documentation quality, clinician time, cost inputs, and implementation barriers.

FDA and institutional decision points

Significant-risk study

Requires an FDA-approved IDE and IRB approval before initiation. [FDA: IDE Approval Process](#)

Nonsignificant-risk study

Requires IRB approval before initiation and compliance with abbreviated IDE requirements. The sponsor presents the basis for nonsignificant risk; the reviewing IRB makes the decision, subject to FDA authority.

Exempt investigation

Any exemption must be supportable under the applicable rule and institutional process. Separate IRB, informed-consent, privacy, contractual, or institutional requirements may still apply.

Official FDA references

- [Premarket Notification 510\(k\)](#)
- [Investigational Device Exemption overview](#)
- [IDE Approval Process](#)
- [IDE Responsibilities](#)

Legal and regulatory review

This guide is a planning resource, not a risk determination, IRB decision, IDE opinion, consent form, investigational plan, or legal advice. The sponsor and institution must make and document the applicable determinations for the specific activity.

Scope a responsible clinical pilot

Use the public inquiry pathway for professional contact and program questions. Do not send patient names, dates of birth, records, images, or other protected health information through public forms, general email, or the website AI assistant.

Professional contact

ISO Metrik Solutions, Inc.
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Atlanta, GA 30342

Phone: (678) 632-3735
Email: info@isometrik.com
Web: isometriktherapy.com

Public pathway links

- [Clinical Evidence](#)
- [Training & Certification](#)
- [Refer or Prescribe](#)
- [DME & Coverage](#)
- [Clinical Pilot](#)
- [Provider & Clinic Sign In](#)

Use boundary

This resource does not replace current product labeling, instructions for use, professional training, licensure, medical judgment, payer policy, supplier requirements, institutional review, or applicable law. Individual clinical and reimbursement decisions belong to the responsible provider, institution, supplier, and payer.