

Developing and sustaining an independent neuromuscular clinical trial site: A practical model from concept to maturity

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Abstract

Independent neuromuscular clinical trial sites serve a vital role in expanding access to novel therapies and improving research efficiency outside traditional academic environments.

This paper outlines the framework, infrastructure, and operational model developed by the Austin Neuromuscular Center (ANC) since 2017. Key elements include facility and safety design, staffing evolution, standard operating procedures (SOPs), regulatory compliance, patient recruitment strategies, budgeting, billing systems, and investigator-initiated trial (IIT) development. The ANC model demonstrates how an independent site can achieve sustainability, regulatory excellence, and innovation, serving as a blueprint for other centers.

Introduction

The rapid expansion of targeted therapies and gene-based treatments in neuromuscular medicine has created an urgent need for a well-organized, community-based research infrastructure. While academic centers have traditionally led this area, independent neuromuscular trial sites now play a crucial role in expanding patient access and speeding up trial processes. These sites combine clinical flexibility, sponsor responsiveness, and strong patient relationships with strict adherence to GCP and FDA standards. This paper shares the journey of the Austin Neuromuscular Center (ANC)—founded in 2017—from its beginnings as a small research extension of a private neurology practice to becoming a recognized, high-performing neuromuscular clinical research site.

Facility and Space Requirements

Establishing a high-quality research environment requires purpose-built space, equipment, and workflow design that prioritize both patient safety and data integrity. The ANC model integrated research operations within an outpatient neurology practice while maintaining regulatory independence and physical separation for audit readiness.

Core Facility Design

- **Research Suite:** Dedicated offices for CRCs and RNs,

private monitoring rooms for sponsors, secure storage cabinets for source documents and signed consent forms, and keycard access to restricted areas.

- **Laboratory Infrastructure:** Equipped with centrifuges, calibrated pipettes, -20°C and -80°C freezers, continuous temperature monitoring with alarm logs, and validated shipping containers. Equipment calibration logs and deviation documentation are maintained in accordance with SOP.
- **Pharmacy and Drug Storage:** Controlled-access room with double-lock system, continuous temperature monitoring, and alarmed cold storage units. Accountability logs and segregation between blinded and unblinded staff ensure regulatory compliance.
- **Infusion Suite:** Two reclining chairs, infusion pumps, continuous vitals monitoring, and ACLS-certified RNs. The suite includes a crash cart, emergency oxygen, an AED, and spill kits.
- **Safety Infrastructure:** The site maintains adverse event management SOPs, annual emergency response drills, and sponsor notification procedures to ensure 24/7 readiness.

Core Team Development and Expansion

Staffing was designed to scale with study volume while maintaining flexibility. Early operations relied on shared roles, with the PI overseeing coordination, budgeting, and recruitment. As the research portfolio expanded, dedicated full-time staff were added.

Table 1. Team Composition and Evolution (2017–2025)

Phase	Team Composition	Key Milestones
2017–2018	PI and 1 CRC	SOP development, first site initiation visit (SIV), first patient enrolled
2019–2021	PI, 2 CRCs, 1 Sub-Investigator, 1 part-time RN	Infusion studies added; expanded sponsor relationships
2022–2025	6 CRCs (2 RNs), 2 RAs, 2 Sub-Is, PRN PT/OT, Research Manager	FDA audits passed, IITs launched, QA oversight established

Staff growth aligned with site expansion.

Standard Operating Procedures (SOPs) and Compliance

The foundation of ANC's operational integrity is a robust SOP framework developed through mentorship and consultation with experienced research organizations. SOPs are reviewed annually, updated as needed, and logged in a master file with version control. In addition, periodic

Figure 1. SOPs Starter Pack (top 12)

- 1) Informed consent
- 2) Source documentation
- 3) AE/SAE; 4) IP mgmt
- 5) Temp monitoring
- 6) Lab processing
- 7) Delegation & training
- 8) Document control
- 9) Screening & enrollment
- 10) Monitoring visits
- 11) Quality audits
- 12) Data integrity & queries

Core SOPs needed for compliant site operations.

internal audits ensure readiness for sponsor or FDA inspections. All personnel undergo GCP certification, IATA shipping training, and site-specific competency assessments.

Study Feasibility and Recruitment Strategy

The site’s success in trial acquisition stems from proactive engagement and data-driven feasibility assessment. The team maintains an internal diagnostic registry of neuromuscular disorders — allowing rapid estimation of eligible subjects for new protocols.

Feasibility Development

- Registered with major CRO and sponsor portals.
- Attended national and international research conferences for visibility.
- Quarterly searches on ClinicalTrials.gov and sponsor websites.
- Maintained a “Site Capability Profile” summarizing infrastructure, historical enrollment, and recruitment strategies, submitted to sponsors during feasibility rounds.

Patient Recruitment

Recruitment combines both internal and external strategies:

- Clinic EMR database of >3,000 neuromuscular patients.
- Referral network of community neurologists.
- Social media and website campaigns.
- Periodic ads in local media and newsletters.
- Incentive program rewarding CRCs and assistants for identifying eligible participants.

This integrated approach allows high recruitment efficiency while maintaining patient retention and engagement.

Budget Development and Billing Management

Transparent and realistic budgeting was essential for sustainability. The ANC team created an internal “Budget Builder Framework” that links each task to an estimated time per role, adjusted for overhead and administrative support.

Figure 2. Feasibility Questionnaire Mastery

Respond in	Respond in 24–48h; honest patient availability; realistic timelines
Highlight	Highlight differentiators: integrated NM clinic, infusion, ALS clinic, EMG, pathology,
Include	Include startup timelines, prior enrollment metrics, screen fail rates

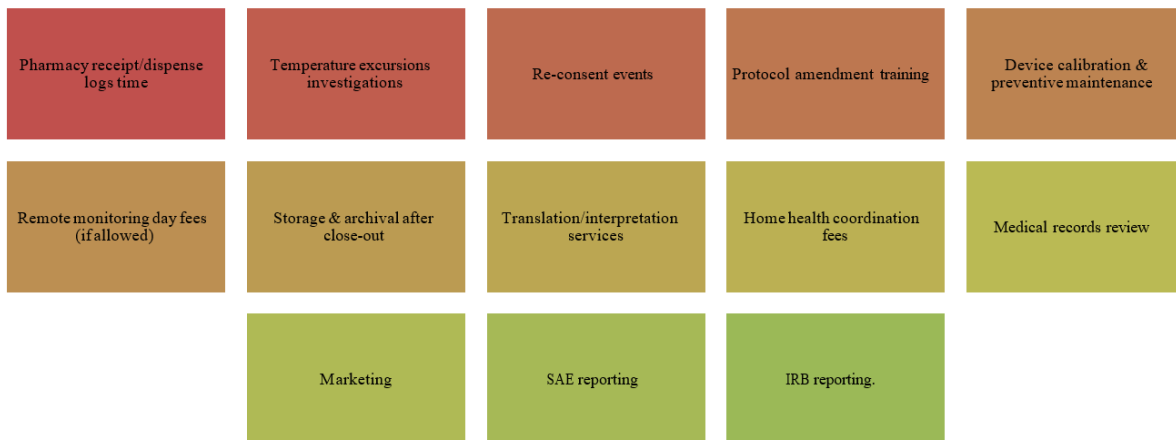
Key elements that strengthen feasibility responses.

Table 2. Budget Builder Framework

Category	Example	Notes
Startup Fees	Regulatory packet, SOP training, pharmacy and lab setup	Non-refundable after SIV
Per-Visit Fees	CRC time, PI/Sub-I review, procedures	Based on time per task
Non-Visit Fees	SAE follow-up, query responses, IRB reports	Often underbudgeted by sponsors
Pass-Through Costs	Labs, shipping, ECG, pharmacy fees	Billed as incurred
Closeout Fees	Archiving, record retention, final QA	Triggered after site closure

Main cost categories used in budgeting.

Figure 3. Commonly Missed Billable Items

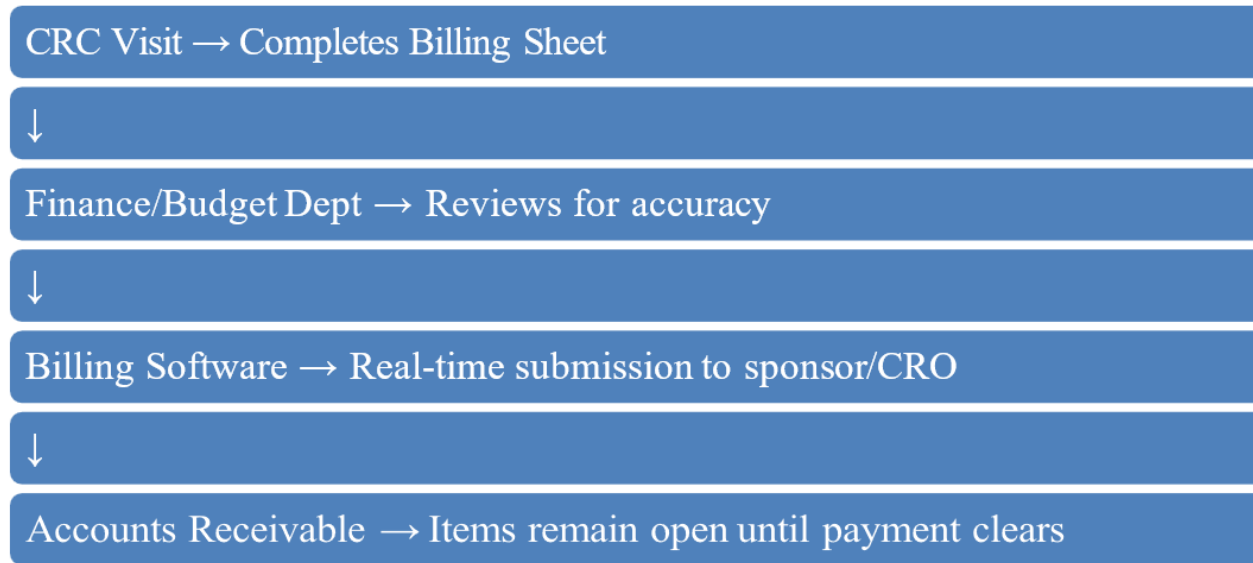


Common tasks that should be captured as billable.

Billing and Invoicing Workflow

Each CRC completes a visit-level billing sheet during each patient encounter, noting protocol-specific billable activities. These forms are reviewed by the Research Manager and entered into real-time billing software for monthly reconciliation.

Figure 4. Invoicing Workflow Diagram



Overview of the internal billing and payment process.

Study Start-Up Timelines

Efficient study start-up is vital for independent neuromuscular clinical trial sites. Unlike academic centers with less efficient administrative processes, private sites like ANC streamline regulatory, contractual, and operational tasks to enable rapid activation and ensure compliance with IRB, GCP, and FDA standards.

1. IRB Approval (Central vs Local)

Central IRBs review applications faster (7–14 days) than local IRBs (4–6 weeks). Many sites prefer central IRBs to minimize delays and enable parallel task initiation.

2. Contract and Budget Negotiation

ANC uses concurrent processes for contracts, budgets, and regulatory approval. This approach typically takes 4–6

weeks for complete agreement, much quicker than academic timelines that may take months.

3. Site Qualification to SIV

The Site Qualification Visit (SQV) assesses site readiness. After SQV approval, ANC aims for 45–60 days to reach Site Initiation Visit (SIV), during which the site begins enrollment.

Prompt responses and pre-prepared SOPs support these timelines.

4. First Patient Screening

From SIV to the first screened patient, ANC achieves 2–4 weeks, thanks to EMR-based recruitment, clinic volume, and trained staff ready to activate recruitment immediately after SIV.

Figure 5. Study Start-Up Timeline



Shows the streamlined activation steps and timeline.

Early-Stage Challenges

Establishing an independent site without institutional backing presented multiple challenges:

- **Human Resources:** Recruiting experienced CRCs was financially difficult during the early phase, with only one or two trials. The solution was to hire part-time coordinators or cross-train clinical staff.
- **Infrastructure and Training:** Initial lack of laboratory and regulatory templates required consultation with experienced PIs and third-party specialists.
- **Financial Risk:** Budget negotiation was handled directly by the PI with mentorship from colleagues; early payment delays from sponsors strained cash flow.
- **Operations:** Infusion studies were initially deferred until infusion capacity and staff competency were developed in later phases.

Despite these barriers, the site achieved steady growth through a stepwise approach emphasizing reinvestment, mentorship, and continuous quality improvement.

Investigator-Initiated Trials (IITs)

Investigator-initiated research represents the most academic and innovative tier of independent site activity. ANC has successfully launched two active and two pending IITs — all open-label pilot studies exploring neuromuscular therapies.

Table 3. Investigator-Initiated vs Industry-Sponsored Trials

Category	Investigator-Initiated Trials	Industry-Sponsored Trials
Funding Source	Institutional or grant-based	Sponsor-funded
Protocol Design	PI-driven and flexible	Sponsor-defined
Cost Efficiency	High, low logistics	Higher operational cost
Oversight	Local QA/IRB	CRO or Sponsor-managed
Innovation	Focused on emerging hypotheses	Focused on registrational endpoints

Quick comparison of operational differences.

IITs enhance clinical creativity and foster academic partnerships, though they demand more internal regulatory oversight and dedicated funding structures.

Operational Performance

ANC’s operational efficiency and regulatory performance highlight the viability of this independent model.

Table 4. Operational Performance Summary

Domain	Outcome
Enrollment	Consistently top 10% across sponsored sites
Retention	<5% subject dropout rate
FDA Audits	Three successful inspections, no major findings
Financial Performance	Timely billing with 95% on-time payment
Team Capacity	6 CRCs, 2 RNs, 2 Sub-Is, PT/OT, Research Manager

Summary of key operational metrics.

Future Directions

The next stage in ANC’s evolution includes:

- Initiation of **Phase 1 and translational studies**, leveraging local pharmacology partnerships.

- Expansion to **satellite research sites** across Texas, following the same SOPs and QA framework.
- Implementation of centralized data systems for remote monitoring and sponsor access.
- Development of a regional **neuromuscular trial network** integrating clinical care, research, and patient advocacy.

Conclusion

The Austin Neuromuscular Center’s evolution demonstrates that independent neurology practices can build sustainable, high-performing clinical trial programs through strategic infrastructure investment, cross-trained personnel, and robust compliance systems.

This model shows that clinical excellence, operational agility, and financial accountability are compatible within an independent framework.

The ANC experience provides a replicable roadmap for other community-based centers aiming to integrate research and clinical care under a unified, scalable model.

Abbreviation Table

Abbreviation	Full Term
ACLS	Advanced Cardiac Life Support
AE	Adverse Event
AED	Automated External Defibrillator
ANC	Austin Neuromuscular Center
CRO	Contract Research Organization
CRC	Clinical Research Coordinator
ECG	Electrocardiogram
EMR	Electronic Medical Record
FDA	U.S. Food and Drug Administration
FPI	First Patient In
GCP	Good Clinical Practice
IATA	International Air Transport Association
ICF	Informed Consent Form
IIT	Investigator-Initiated Trial
IP	Investigational Product
IRB	Institutional Review Board
Sub-I	Sub-Investigator
Lab	Laboratory
NM	Neuromuscular
OT	Occupational Therapist / Occupational Therapy
PI	Principal Investigator
PRN	As needed
PT	Physical Therapist / Physical Therapy
QA	Quality Assurance
RA	Research Assistant
RN	Registered Nurse
SAE	Serious Adverse Event
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
SQV	Site Qualification Visit
V	Study Visit