

Patient Recruitment Modality Guide

Audience: Site networks and sponsors/CROs running centrally managed recruitment

Goal: Match recruitment channels (advertising, referrals, data-driven outreach) to study type and patient population—executing centrally without overwhelming sites.

How to Use This Guide (60 Seconds)

- **Page 1:** Background & principles — read once.
- **Page 2:** Picker (decision tree + matrix) — use for each protocol.
- **Page 3:** Evidence & policy references — paste into IRB/compliance packets.
- **Page 4:** 6-week pilot plan — launch & optimize.

(Optional Page 5 add-ons: Compliance Quick Ref, Attribution Blueprint, KPI Dictionary, Templates.)

Background and Principles

Why modalities matter

Enrollment shortfalls remain endemic; single-channel plans underperform. Channel performance varies **by study archetype** (rare vs common; biomarker vs symptomatic), **population** (pediatric, older adults, under-represented), and **model** (site-based vs hybrid/DCT). The fastest path to randomization blends intent-driven digital (search/social), data-driven outreach (EHR/portals/registries), and trusted human referral-within tight privacy and platform guardrails.

Six Core Principles for Central Campaigns

1. **Design to randomization, not clicks.** Optimize to CPRZ (cost per randomized), not lead volume.
2. **Let study & population dictate mix.** Rare/biomarker → registries/labs/EHR; common chronic → search + social; pediatric/older → caregiver flows + phone.
3. **Blend channels to correct skews.** Pair EHR portals and social ads to balance demographics.
4. **Privacy by design.** No PHI to ad platforms; follow HIPAA/OCR tracking-tech bulletins and TCPA rules.
5. **Centralize friction, localize trust.** Central prescreen + bilingual call center; warm handoff to sites within 24–48 h.
6. **Equity from Day One.** Monitor funnel by race/ethnicity/language/ZIP; shift budget toward under-reached segments; align to FDA Diversity Plans.

Compliance Callouts

- **IRB review** of all ads and screeners.
- **HIPAA/OCR 2024 tracking-tech guidance:** ban pixels or SDKs on PHI pages; use first-party analytics.
- **FTC Health Breach Rule:** no sharing of health data for ads without explicit consent.
- **Ad Platforms 2025:** Google disallows personalized targeting on sensitive health; Meta bars implying knowledge of conditions.
- **TCPA:** Maintain opt-in logs; STOP keyword compliance for texts; no auto-dialing without consent.

Picker (Decision Tree + Matrix)

A. 30-Second Decision Tree

1. **Rare or genotype/biomarker-gated?** → Registries / Labs / EHR + KOL referrals; advocacy emails; avoid broad social.
2. **Common chronic (T2D, obesity, derm, respiratory, women’s health)?** → Search + Paid Social + CTV + Site DB reactivation; bilingual support.
3. **Oncology?** → EHR & tumor boards + ePRO alerts + clinician referrals; supplement with second-opinion search ads.
4. **Pediatric/adolescent or caregiver-led?** → Caregiver social + school flyers (Peachjar) + pediatric portal messaging.
5. **Older adults/mobility limits?** → Facebook + Direct Mail/Phone + POC media; large fonts, caregiver CTA.
6. **Under-represented groups?** → Community/faith/barbershops/CHWs + bilingual creative + translation budget.
7. **Hybrid/DCT?** → Digital lead-gen + remote eConsent + home health; nearest hub handoff.

B. Modality Matrix

Study/ Population	Primary Modalities	Plus-Ups	Use Sparingly / Avoid	Operational Notes
Rare / Genotype	EHR queries; Registries/Lab partners; KOL referrals	Advocacy emails/newsletters; precision search	Broad social ads	Legal/ethical re-contact; IRB pre-approval.
Oncology	EHR & Tumor Boards; ePRO outreach; Clinician referral	NCI/Advocacy matching; high-intent search	Display ads	Navigator callbacks < 24 h; simplify eligibility copy.
Metabolic/CV/Derm/Resp	Search + Paid Social + CTV; Site DB reactivation	PCP fax; Pharmacy partners	Letters-only	Negative keywords; bilingual line; 24 h callback.
Women’s Health/Fertility	Search + Community Influencers (FTC-compliant)	OB/GYN referrals; Advocacy	Pixeling PHI pages	Separate consent and tracking; privacy review first.
CNS/Mental Health	Search + Social; Telehealth lists	PCP/Therapist referral	OOH only	Short screen; confidentiality emphasis.
Pediatrics	Caregiver social/search; School flyers; Pediatric portal	Parent forums	Direct targeting of minors	Parent-first UX; assent language.
Older Adults	Facebook; Mail/Phone; POC media; CTV	Caregiver targeting	Mobile-only flows	Phone option; large font; mail-back forms.
Under-represented Groups	Community/CHW + Bilingual creative	Local radio; Ethnic press	English-only funnels	und CHWs; translate consents; hire bilingual staff.
Hybrid/DCT	Digital lead-gen + Remote eConsent + Home Health	Local labs/ECG hubs	Site-only walk-ins	Tech support; device logistics; state licensure review.

Evidence and Policy References

(Copy these into IRB appendices or sponsor decks as needed.)

EHR & Clinician Workflows:

- Navar AM et al., JAMA Netw Open 2025 — Portal invitation engagement.
- Verdini NP et al., JAMA Oncol 2024 — ePRO outreach ↑ enrollment vs MD referral.
- VCU CCTR 2024 — Epic BPA best practices.
- Daniels AM et al., J Clin Transl Sci 2023 — SPARK multimodal recruitment.

Digital & Social Advertising:

- Darmawan I et al., JMIR 2020; Oudat Q et al., 2023; Goldman N et al., 2023 — Social media recruitment ROI meta-analyses.
- Baldyga K et al., J Am Geriatr Soc 2025 — Older-adult web ads faster than traditional.

Community Models:

- Victor RG et al., NEJM 2018; Kazi DS et al., Circulation 2021 — Barbershop/pharmacy trust frameworks.
- Pardhan S et al., Int J Equity Health 2025 — Minority recruitment barriers & solutions.

Pediatrics/Caregiver

- Bouma-Sims E et al., arXiv 2024 — School e-flyer (“Peachjar”) feasibility study.

DCT & eConsent

- Jean-Louis G et al., Science 2024 — DCTs ↑ inclusion & speed.
- Bikou A et al., JMIR 2024 — e-recruitment & consent best features.

Recruitment Difficulty Baseline

- Brøgger-Mikkelsen M et al., JMIR 2020 — ≈ 80% of trials miss enrollment targets.

Policy Snapshot (Nov 2025)

- HIPAA/OCR Tracking-Tech Guidance (2024).
- FTC Health Breach Notification Rule (GoodRx case).
- Google Ads Sensitive-Health Policy (May 2025).
- Meta Health/Wellness & Personal Attributes Policies (2025).
- FDA Diversity Action Plans (2024 draft).
- TCPA Consent & Revocation Updates (2024).

6-Week Pilot Plan (Launch & Optimize)

Objective: Validate channel mix and operational flow to CPRZ targets while meeting diversity goals.

Week 0–1: Foundations

- IRB approvals (ads + landing pages + scripts).
- Privacy audit — remove third-party pixels from PHI pages.
- Stand up central prescreener + bilingual call center (24 h SLA).
- Site readiness — referral acceptance ≤ 48 h; warm-transfer workflow.

Week 2–3: Launch & Learn

- Deploy Search + Meta/YouTube + EHR portal messaging in 2–3 metros.
- A/B test 3 headlines, 2 images, Spanish variant.
- Measure Lead \rightarrow Prescreen \rightarrow Eligible \rightarrow Randomized.

Week 4 : Broaden & Balance

- Add advocacy newsletters + community placements.
- Enable EHR BPAs at top sites.
- Check the equity dashboard (race/ethnicity/language/ZIP).

Week 5–6 : Optimize & Scale

- Scale channels meeting CPRZ and conversion thresholds.
- Pause underperformers; expand languages; add CTV for reach.
- Publish readout with CPRZ, diversity mix, screen-fail drivers.

Go/No-Go Gates

- $\text{CPRZ} \leq \text{target } \$ / \text{ randomized}$
- $\text{Screen-fail} \leq \text{defined ceiling}$
- $\text{Diversity} \geq \text{floor per FDA plan}$
- $\text{Site response} \geq Z\% \text{ within } 48 \text{ h}$