

How to Create a Patient Recruitment & Retention Plan

CORE ELEMENTS AND PROCESS STEPS

Everything you need to know about creating a patient recruitment and retention plan!

HIGH LEVEL OVERVIEW

STEP 1



HOW MANY PATIENTS ARE NEEDED?

Conduct a recruitment funnel analysis to determine how many candidates need to be identified, pre-screen qualified, consented and screened in order to meet the randomization goal.

STEP 2



WHERE WILL THE PATIENTS COME FROM?

Create a "Patient Pathway" to determine the primary sources of subjects and estimate the percentage of subjects that will come from each source to determine whether a Patient Recruitment Organization (PRO) will need to be involved.

STEP 3



WHAT TACTICS ARE NEEDED TO RAISE STUDY AWARENESS?

Create a list of tactics for building study awareness within each source of patients and determine the materials and messaging and estimated budget that will be needed to recruit the patients.

ESTIMATE THE BUDGET AND DOCUMENT THE PLAN:

Confirm and document the study level plan; adapt for each country and customize for each site as appropriate.

RECRUITMENT FUNNEL ANALYSIS

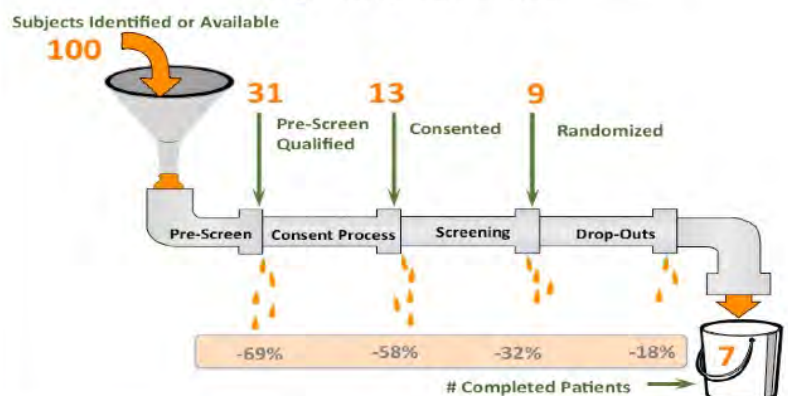
THE TYPICAL RECRUITMENT FUNNEL

Industry benchmark data suggests that on average, you will need to identify 10 times as many subjects as you plan to randomize.



The "Typical" Recruitment Funnel

Average Industry Benchmark Data





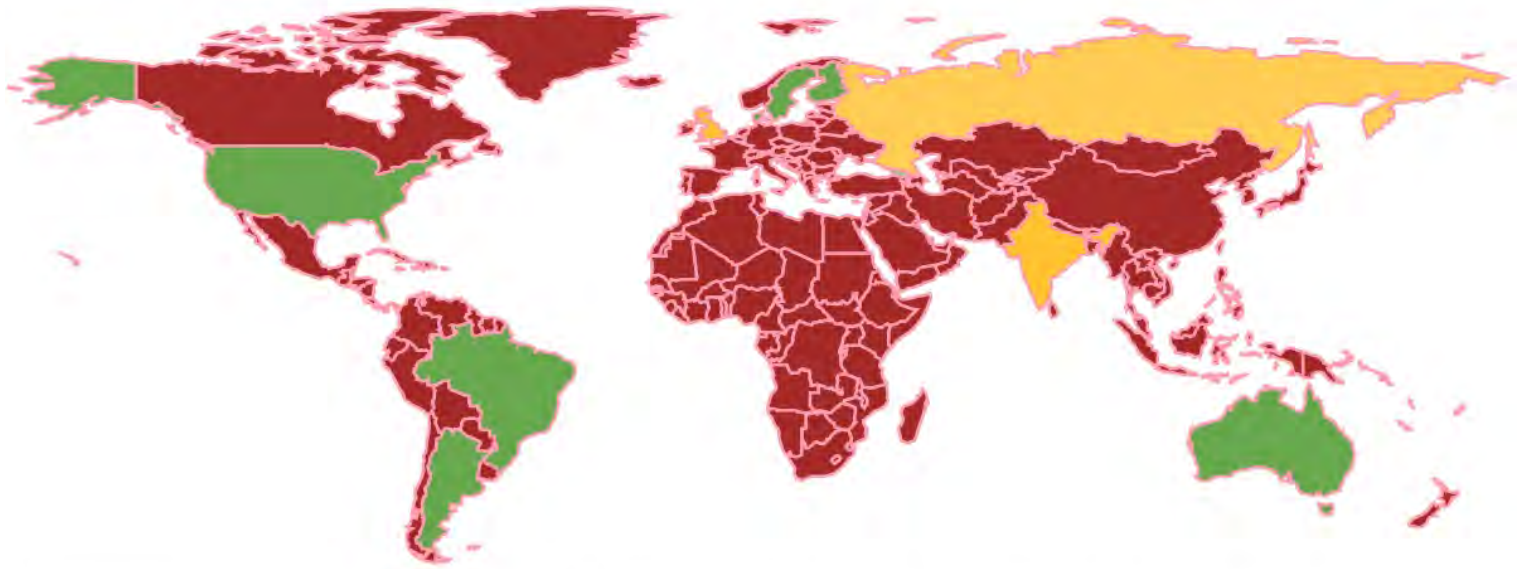
VALIDATE ENROLLMENT POTENTIAL

Confirm the estimated recruitment funnel by setting up a contract and conducting a paid enrollment validation assessment with select sites and/or a data analytics services provider.

Identify potential opportunities to modify the eligibility criteria to make this less restrictive.

If this is not feasible or if in doubt, plan to reach at least 10 times more subjects than you need to randomize!

EVALUATE DISEASE PREVALENCE AND COUNTRY ALLOCATION



Evaluate disease prevalence to determine countries with available subject population.

Compare initial country list based on enrollment potential, with countries that can fulfill strategic and regulatory objectives.

Create "short list" of countries in which to conduct further feasibility evaluation.

DETERMINE LOCATION AND SOURCES OF SUBJECTS

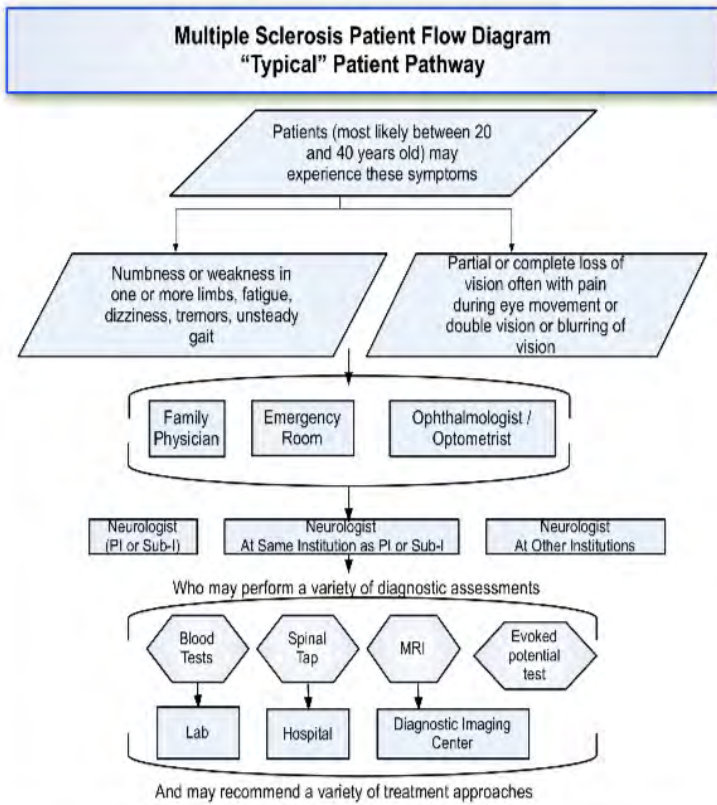
Work with internal and external experts to create a "Patient Pathway" to illustrate how patients navigate through the healthcare system, which types of healthcare professionals (HCPs) they encounter and what the typical standard of care treatment options look like.

This will help to determine the appropriate type of site profile as well as where the clinical trial fits into the patient care continuum.



USE THE PATIENT PATHWAY TO:

- ▶ Determine which type of specialist(s) is most appropriate to serve as the principal investigator.
- ▶ Identify other types of HCPs that may interact with the patient and who could be sources to identify or refer patients, or may influence the patient's decision to participate.



Prioritize sources for "Filling the Funnel"

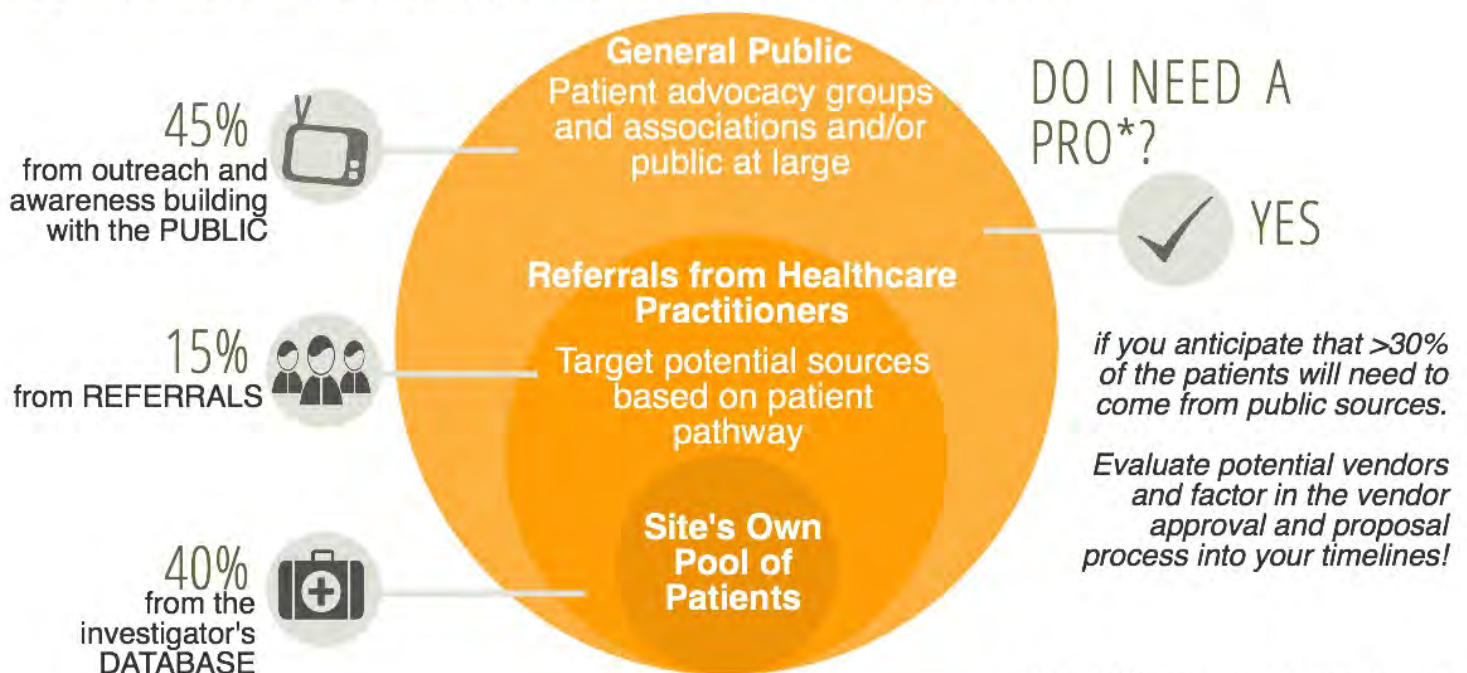
Ophthalmologists
Emergency Department
Physical Therapists
Pharmacist
Social Workers

Patient support group
Internet websites
Pharmacies



- ▶ Identify various influencers; those who may influence the patient's decision to participate and who needs to be engaged in the process
- ▶ Assess where else the patient (and/or family) may seek additional information from and whether these sources could serve as potential places for building study awareness.

ESTIMATE THE CONTRIBUTION FROM EACH SOURCE



*Patient Recruitment Organization



GENERATE IDEAS FOR MATERIALS AND MESSAGES TO BUILD STUDY AWARENESS:

Tactics for keeping study team / CRO engaged

- Monthly teleconference with Medical Monitor
- Talking points and tips sheet for the CRAs and Site Relationship Managers

Tactics for keeping study top of mind with investigative sites

- Create a study "brand" (logo and acronym)
- Study portal with FAQs
- Protocol simulation workshop at Investigator Meeting
- "Tip of the week" e-blast
- Quarterly visit from Site Relationship Manager

Tactics for educating and engaging HCPs

- Approved PowerPoint presentation for educational session
- Funding and worksheet for patient pre-screening
- Thank you for referring your patient note card

Tactics for making potential patients aware of the study

- Funding and materials for health fairs
- Advertisement for patient association newsletter
- Poster for pharmacy and physical therapy clinic

CONFIRM AND CUSTOMIZE TACTICS, MATERIALS AND MESSAGES



VALIDATE THE RECRUITMENT TACTICS WITH SITES!

High Tech or High Touch Tactics?



Before investing in and finalizing any materials or messages be sure to assess appropriateness of tactics at the country level and confirm site interest and willingness to use the materials.

Evaluate ethics approval and translation requirements.

Prioritize the tactics most likely to generate the best return on investment (based on prior metrics). Consider central as well as locally implemented tactics.

Generate budget and determine internal approval requirements.

ESTIMATE ENROLLMENT PERIOD & PERFORMANCE METRICS



Create best case, realistic case and worst case scenarios for enrollment timelines.

Determine criteria for evaluating success of various recruitment initiatives.

Consider some "What if" scenarios for things not going according to plan and factor in some contingencies



DON'T FORGET ABOUT MAXIMIZING THE CONVERSION AND RETENTION OF PATIENTS!

Work with internal and external experts (e.g., operational advisors, patient association representatives) to identify all of the potential "leaks" at the pre-screening, consenting, screening and retention stages.

What are all of the potential barriers to successfully converting the identified patient through to a completed and compliant patient?

"Filling the Funnel" of patients just one part of the plan. It's equally important to identify opportunities to "manage the leaks" along the patient participation pipeline.



Which of the barriers can be addressed (while respecting all GCP principles) and how?

Factor into the budget any initiatives to support efficient pre-screening, patient education, patient transportation and so forth.

DOCUMENT AND REGULARLY EVALUATE THE PLAN

IF IT ISN'T DOCUMENTED IT WON'T GET DONE!

RECRUITMENT STARTS WITH THE PATIENT BUT "HAPPENS" AT THE SITES. ENSURE SITES HAVE A RECRUITMENT ACTION PLAN (RAP) THAT CAN BE USED TO MANAGE SITE LEVEL ACTIVITIES.



BUDGET

INCLUDE:
Payment for pre-screening work effort, materials development and translation, local and centrally supported outreach and awareness activities as well as retention support items.

DOCUMENT

STUDY, COUNTRY AND SITE LEVEL PLANS:
This allows you to manage the implementation at the country and site level and serves as a good record for future studies.

EVALUATE

MONITOR AND UPDATE THE PLANS FREQUENTLY:
Determine what is and isn't working, analyze the root causes of why not and adjust the plan or trigger contingency initiatives if needed.

DELIVER

ON TIME ENROLLMENT:
Failing to plan is planning to fail. Incorporate all of these best practices to deliver on-time and on-target enrollment and retention!

FOR ADDITIONAL RECRUITMENT PLANNING INFORMATION CONTACT:
Beth Harper; Clinical Performance Partners, Inc.
817-946-4782; bharper@clinicalperformancepartners.com

