

Recruitment Funnel Calculator

High Level Site Enrollment Validation Assessment – Job Aid

As part of the study feasibility and enrollment validation process, it is important that sponsors and sites gain a shared understanding of the enrollment expectations and feasibility of achieving the enrollment goals. This is an essential step to ensure fulfillment of International Conference on Harmonization (ICH) Part 4.2.1 which states that “The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.” The Recruitment Funnel Calculator helps sites determine a more realistic assessment of the enrollment potential at your site.

Enter the planned enrollment period as provided by the sponsor or CRO. Enter “1” for the # of sites as this job aid focuses on site level vs. study level planning.

Over the course of the expected enrollment period (e.g., 12 months), on average how many patients with {Disease Indication} do you typically see in your practice?

TIP: Run an EMR or billing system / CTMS search on the high level diagnostic criteria (e.g., ICD-9) code to get a sense of the # of patients with the diagnosis of interest seen in the last XX months (e.g., 6, 9, 12 or whatever the planned enrollment period is). Enter that # here.

While it is difficult to project a drop-out rate at this stage, industry data suggests that we can anticipate an approximate drop-out rate of 18-20%.

How does this compare with your experience? Do you think you will lose more or less than this % of patients over the course of the study? Based on your review of the protocol synopsis, what do you think is a reasonable estimate of the drop out ratio for this study?

Enter the percentages here and/or use the benchmark data.

Recruitment Funnel Calculations

“Top Down” Funnel Calculations

Funnel Parameters and Stages	Values
Enrollment Period (months)	12
# of Sites	1
# Patients at a Given Site with Diagnosis or # Patients Available Across All Sites	100
% Lost During Pre-Screening	0.69
% Decline to Participate	0.58
% Lost During Screening	0.32
% Drop-out Post Randomization	0.18

Funnel Calculations	Projected Values
Patients Available	100
Pre-Screen Qualified	31
Consented (Enrolled)	13
Randomized	9
Completed	7
# Enrolled / Month	1

Available: Randomized Ratio = 11 to 1

Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	100.0	8.3
# That Will Need to Be Pre-Screened	31.0	2.6
# That Will Need to Be Consented	13.0	1.1
# That Will Need to Be Randomized	8.9	0.7

Key:

Starting # Enter Here
Enter Data in These Fields
Calculated Field

Industry benchmark data) suggests that ~2/3rds of the patients with a given diagnosis will fail the pre-screening criteria*.

How does this compare with your experience? Do you think you will lose more or less than this % during pre-screening?

Based on your review of the protocol synopsis, what do you think is a reasonable estimate of the pre-screening loss percentage? Enter the % here.

If time doesn’t allow a thorough validation exercise (EMR search, sample chart review), be conservative and use the benchmark data.

Benchmark data estimates the following loss rates at the informed consent and screening stages. How does this compare with your experience? Do you think you will lose more or less than this % during consent and screening phases? Based on your review of the protocol synopsis, what do you think is a reasonable estimate of the loss percentages at these stages?

Enter the percentages here and/or use the benchmark data if you aren’t able to do a more thorough analysis.

Based on the number of potential patients you have available, and applying these loss rates “through the funnel”, it appears that you could realistically enroll (consent) _____ patients and randomize _____ patients into the study during the expected enrollment period. This translates to an enrollment rate of ____ (e.g., 1.1 or 0.7) patients per month.

TIP: Do a reality check; do these estimates (along with the overall conversion ration) seem reasonable overall compared to your past experience in similar trials. Does this raise any potential “red flags” about resource requirements?

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A “bottom’s up” or Reverse Funnel Calculation can be helpful to run some “what if” scenarios. What if the sponsor requests a minimum # of randomized patients, what impact will this have to the # of patients that need to be identified outside your practice? What if the consent decline (or any other) ratio is worse than we expect? What if, the enrollment period is shortened, how will this impact your workload, etc. This example will look at the impact of changing two parameters.

Say the sponsor requires a minimum of 20 randomized patients. Starting at the bottom of the funnel enter the new estimated contribution.

What if a higher percentage of subjects are expected to decline the study? Enter the new % (in this case 75%) in the blue fields above.

You will need to identify some _____ # patients (e.g., 380) with the diagnosis. This translates to an enrollment rate of _____ # (e.g., 2.5 patients per month). The overall conversion ratio changes from 11 to 19 to 1.

What does this mean from a study awareness and site resource perspective? You previously identified access to only 100 patients with the core diagnosis that were seen at your institution within the last year.

What additional sources of patients could you tap into and realistically how many patients do you think you would be able to identify from each source? Are these sufficient numbers to make up the gap?

- Source 1: _____ Approx. # _____
- Source 2: _____ Approx. # _____
- Source 3: _____ Approx. # _____
- Source 4: _____ Approx. # _____
- Source 5: _____ Approx. # _____

What type of materials and resources do you think you will need to reach these patients (e.g., dinner meetings with physician colleagues, advertising, etc.)?

What impact do you think that this will have to your site resources? Do you feel that you have sufficient staff to conduct the study awareness / outreach efforts required to reach these patients from the external sources?

What additional staff or support would be needed to support your efforts in identifying and pre-screening these patients (e.g., reimbursement to conduct chart reviews, on-line pre-screening of patients or use of a call center, etc.)?

Reverse or “Bottom Up” Funnel Calculations

Funnel Parameters & Stages	Values
Enrollment Period (months)	12
# of Sites	1
# Patients That Will Need to Be Identified	380
% Lost During Pre-Screening	0.69
% Decline to Participate	0.75
% Lost During Screening	0.32
% Drop-out Post Randomization	0.18

Funnel Calculations	Projected Values
Patients That Need to Be Identified	379.5
Pre-Screen Qualified	117.6
Consented (Enrolled)	29.4
Randomized	20.0
Completed	16.4
# Enrolled / Month	2.5

Available: Randomized Ratio = 19 to 1

Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	380	31.6
# That Will Need to Be Pre-Screened	118	9.8
# That Will Need to Be Consented	29	2.5
# That Will Need to Be Randomized	20	1.7

Is there anything else that you can think of that could be done to minimize the number of patients that are lost through:

The consent process? _____

The screening process? _____

Is there anything else that would help minimize the burdens or inconveniences of study participation and ensure the likelihood that a patient would be willing to enroll as well as stay in the study?

Brainstorm on these ideas with your internal colleagues, CRAs and other sponsor/CRO personnel. Try to ascertain what type of recruitment / retention support will be available. Based on this information you may need to re-assess whether this study is a good fit, re-negotiate enrollment expectations with the sponsor/CRO and/or respectfully decline the opportunity.

* Pre-screening involves activities that can be done to determine potential eligibility through database search, chart review, phone interview, etc. whereas screening involves study-specific physical assessment of the patient performed after informed consent is obtained. Pre-screened patients can be considered to be “matched” to a sub-set of the key eligibility criteria (the top 5-10 key eligibility criteria..