



The Importance of Conducting Protocol-Specific Feasibility

Identifying the Right Sites Requires a Protocol-Specific Feasibility Study

Targeting the Right KOL Networks and Sites Is Critical to Success

As the drug development industry struggles to improve clinical trial efficiencies to speed up the process of bringing new therapies to market, we look to one of the most common and costly delays for trials – patient recruitment. With nearly 80 percent of patient recruitment timelines in clinical trials not being met and over 50 percent of the patients not being enrolled within the planned timeframes, the sooner we identify where to find our patients, the better. Conducting protocol-specific feasibility early on is a vital contributor to targeting the right Key Opinion Leaders (KOLs) and clinical trial sites to start-up a successful trial.

Challenging the Status Quo

Recently, a biopharmaceutical firm approached us to develop a recruitment plan for its Osteoporosis program. Our client had identified and expected us to engage with the usual KOLs for an Osteoporosis study – including sites in Arizona and Florida – selected for their high levels of aging patient populations. We ran an initial feasibility study for the typical sites, and they assured us they could recruit a minimum of 10 patients each.

Our project team received the final protocol and discovered a nuance in the inclusion criteria that might affect site selection. The inclusion criteria required that the patients with osteoporosis be treatment naïve for the last six months. We re-connected with all the sites to speak with them about the new requirement. Many of the KOLs/sites that we initially contacted could no longer recruit a single patient, as their patients were currently being treated with other osteoporosis therapies. This analysis and discussion led us to change the parameters of our site selection process.



~80%
of patient recruitment
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>50%
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enrolled on schedule



It is critical to perform your feasibility specific to your study protocol and re-connect with sites after any protocol changes.”

Shaheen Limbada, EVP Global Clinical Operations
at Veristat

Finding the Right Sites Based Upon Inclusion Criteria

We turned our focus on identifying sites with high volumes of patients with new fractures and sites with a referral network established from local fracture clinics. By evaluating sites with these new criteria, we were able to build a new list of sites that would be able to recruit the necessary treatment naïve and even newly diagnosed osteoporosis patients.

When we presented the new list of sites to our client, they were shocked and questioned why the known sites and KOLs weren't on the list. When we explained to them that the typical sites and KOLs couldn't enroll patients based on their protocol's requirements, they were so thankful that we did the feasibility on their specific protocol.

The Impact Saves Time:

Veristat identified the right sites to get the study going quickly for the client. We avoided the delays that would have occurred if the study began with the original list of sites.

Recruitment Focus:



Sites with high volumes of patients with new fractures



Sites with referral networks from local fracture clinics

Feasibility Is the First Step, But Just the Beginning of the Patient Recruitment Journey

Conducting a feasibility and particularly a live and protocol specific feasibility is the first step in improving the efficiency of a clinical trial. A live feasibility typically takes 2-3 weeks to conduct in order to gather preliminary basic information about the numbers of patients a site estimates they can recruit, and the numbers of patients seen for the disease state being evaluated. When a live feasibility is unable to be done, sites are identified and numbers of patients are estimated through epidemiology analysis, literature review and evaluation of competitive studies. The only accurate prediction of your patient recruitment and site enrollment funnel, comes from real-time conversations with the sites on a daily, weekly and monthly basis. That is where Veristat excels.

THE FEASIBILITY PROCESS: *Best Practice to Develop Questionnaire – Use Final Protocol*



Identify Sites



Develop
Questionnaire



Send Survey
to Sites



Call/Speak
To Sites



Build Recruitment
Plan & Timelines

Contact Veristat Today

Learn more about Veristat and how we can assist you with strategic program planning, patient recruitment, site management, biometrics, or regulatory submission support.

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