

Where To Find Good Clinical Trials Sites And How To Make Them Better



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Stock, options and consulting VistaGen Therapeutics; consulting Otsuka, Sumitomo
Dainippon and PPD



Clinical trials contracts AbbVie, Otsuka, Oryzon, Janssen, Idorsia Relmada, Karuna,
• Supernus, VistaGen



Site Culture is Very Important

A good site should be committed to:

- The rigor of its studies and the reliability of its data
- The welfare of its study subjects during and after the trial
- The job satisfaction of its staff
- The financial stability and profitability of the site

My Background and Experience

I directed an academic research site at Columbia/NYSPI for 20 years

I have owned and directed a private clinical trials site for 20 years

I have interacted with several private equity groups who were interested in purchasing my site

I have been in multicenter trials being conducted at all three types of sites

Academic Clinical Trial Site

Positives

- Scientific and clinical standards usually high, plus institutional oversight
- Less financial incentive to “cut corners”

Negatives

- Bureaucracy slows things down, especially re startup
- PI has less control re hiring, firing, allocating resources and may not be incentivized to enroll well

Principal Investigator Owned Site

PI determines the culture of the site, for better or for worse.

Site has to balance rigor and ethics with desire to maximize enrollment and profit.

Given the subjective elements in psychiatric research, the site's commitment to clinical rigor is very important.

Private Equity Owned Site

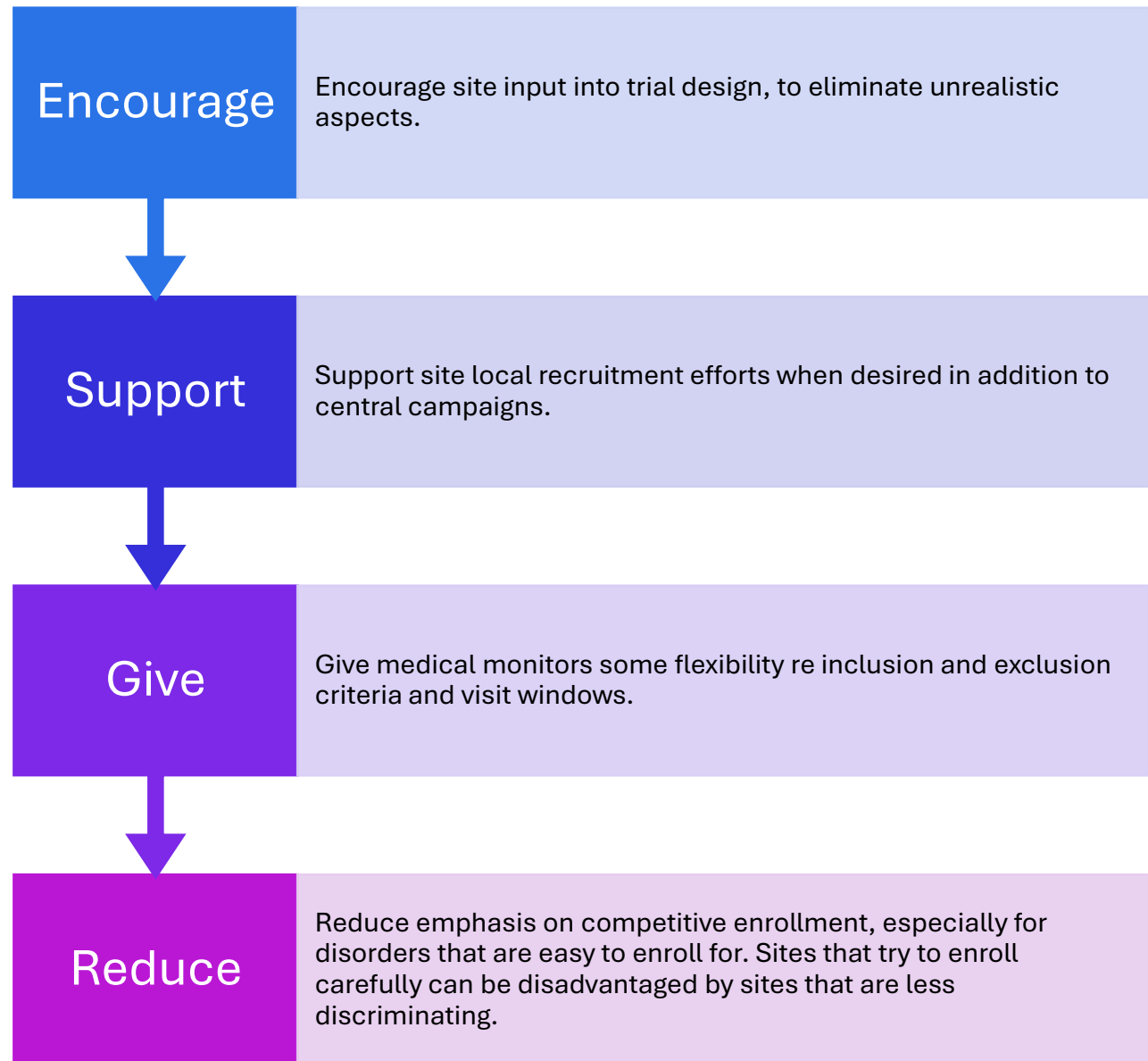
Usually produces more sophisticated accounting, record keeping, HR, etc.

Usually standardizes site culture, which can be positive or negative

When PE acquires a PI site, how long PI will continue can be uncertain

Will a site's culture change when acquired by more financially savvy PE?

How To Enhance Site Performance



Questions for Sponsors and CROs

How to recognize and pick good sites

How to foster site excellence

How to design trials that meet sponsor goals
but also make clinical sense for subjects and
commercial sense for sites

Do these issues differ for academic, PI owned
and networked sites

Questions for Sites

How to best interact with sponsors and CROs

How can sites insure that trials make sense clinically for subjects and commercially for themselves

Should sites insist on reasonable or even robust local recruitment budgets even if the sponsor is planning a centralized recruitment campaign