

# Selecting Quality Sites During the Great Pandemic Power Shift

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# Disclosures

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# Clinical Trials in the Current Climate

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Lookback on climate: 3 yrs ago vs last 6-9 months

The business of running trials has changed

Are we designing ourselves out of practicality?

Are the decisions around use of technology helping or hurting during the greatest labor crisis and period of individual power?

Characteristics of successful trials in current climate: flexible, responsive, in tune, in touch, addressing burden, listening to sites, identifying the sites that can function in this environment

Sites may be moving into the “power” position much like employees are in the labor market

# The Current Site Experience

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The Great Resignation across all industries has had an overwhelming effect on how sites can perform in 2021 and 2022.

All employers with large turnover suffer from not only staff shortages but also the time and effort to find, hire, and train new employees

Day-to-day work becomes constrained

Based on surveys with top performing sites:

- Sites then have to make hard decisions about the work they take on
- Sites also have to re-prioritize even after they have decided to take on studies that become time-intensive

# The Current Sponsor Experience

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Starts with basic, normal need for quality site performance, appropriate patient population, and ability to enroll in allotted time

Now an even greater need for sites who can perform during a shortage of sites that cannot

Maintaining same level of site qualifications may need reconsideration in the current environment

Coming to realize that quality with practicality of design needs to be considered

# The Current Patient Experience

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Patients have more access to clinical trial information than before through the internet, social media, and word of mouth

They know the value of their time more than before: cost of participating vs reimbursement (plasma donation vs stipend)

They can participate in more trials than before even when they are remote

They are not motivated to help us understand how digital technology works in a clinical trial

Patients' trust in clinical trial sites is reportedly diminishing and sites are aware of this, causing some sites to decide which studies are best for their patients

# High Performance Sites

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Under the conditions of a site network, which includes: predictable work volume, grant reimbursements that align with true costs to conduct work, and relationship management, a selection of sites can regularly outperform the standard site on these performance indicators:

Range from 20-50% improvement on the average site performance:

- Time to executed contract
- Start-up timelines including initial feasibility
- Time from site initiated to first patient enrolled

155% increase in # of randomized subjects for network sites

# Selection of Sites

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Investigator grants lag in benchmarking when new assessments and technologies enter into the scene

Country	2018-2020
Czech Republic	10%
Germany	19%
Hungary	18%
Poland	11%
Spain	24%
Taiwan	0%
United States	14%

Grants have increased in most countries from 11-24% over the years 2018-2020.

Early study design and methodology decisions will impact site eligibility

- Protocol complexity and burden
- Number and types of technology

Sites have variables that are difficult to control that influence how they perform: labor market, sponsor study design decisions.

The future: Will we be selecting sites or will sites be selecting us?