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# Navigation Through FAIR MARKET VALUE AMBIGUITY

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Determining Fair Market Value (FMV) benchmarks are a vital factor to global compliance with increasing emphasis on regulations including the Physician Payments Sunshine Act, the Loi Bertrand, and the EFPIA Disclosure Code. Consideration must also be given to how these details affect negotiation and overall study start-up timelines as well as on-going Sponsor-Site relationships. Effectively managing the negotiation ensures that the budget meets compliance regulations and further sets the expectation for future endeavors between a Sponsor and a site.

Establishing FMV, however, is well-known to be an opaque subject with lack of clearly defined guidelines. Interpretation of official definitions published by the Office of Inspector General, Centers for Medicare and Medicare Services 42 CFR 411.351, and IRS Publication 561 is subjective to an arms-length, at best. Data-driven solutions based on percentiles of actual negotiated contracts help to provide context to site and procedural costs at country, phase and indication levels; however, diligent negotiations often reveal that constraining discrepancies still exist on what Sponsors consider fair in comparison to what sites consider actual costs incurred. Benchmarks alone do not constitute a solidified end point for costing; particularly where regional markets may dictate substantially different expenses within a small radius.

Thorough comparison of historically negotiated budgets across multiple Sponsors and studies provides additional depth of visibility into market costs at the site-specific level, including:

- Consistency in site unit and staff costs that are aligned to well defined rationale and documentation, regardless of contracting Sponsor;
- Analysis of additional effort related to the complexity of the disease indication and Protocol design;
- Medicare coverage analysis;
- Administrative and ad hoc costs that are justifiable in relation to the amount of time and effort associated with a specific study;
- Documented overhead costing that is comparable to similar sites and similar regional markets; and
- Reasonable expectations for cost increases, including overhead and over-defined time points (12-24 month window).

Methodical and accurate budget development is a key link to the execution timelines of clinical trial agreements (CTAs) as well the ability to perform investigator payments. Every week lost to negotiating a CTA with a site represents a week of patients potentially lost to enrollment, a week of data not collected, and a week that threatens the timelines of the study. Building an investigator budget upon reasonable and defensible fair market value data reduces weeks lost in budget negotiations with sites. Multiplied across several hundred sites, these weeks represent substantial costs in time and resources to the study, as well as increase the risk of sites dropping participation in the research altogether. Ultimately, active site participation is essential for the crucial work of screening and enrolling patients as well as accurately reporting study data in a timely fashion. ●