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How Sites and Sponsors in the Clinical Research Industry Can Best Contribute to Determining Fair Market Value

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Introduction:

Everyone has experienced being either a buyer or seller of something at one point in their lives- and therefore by default are familiar with gaining or giving value for a monetary exchange. Whether you are the buyer of a \$1 cheeseburger or the maker and seller of the same \$1 cheeseburger, you understand there is a value being exchanged by both parties. This agreement of exchange establishes, what is commonly referred to as, a fair market value of \$1 for the cheeseburger.

Definition:

Merriam-Webster defines fair market value (FMV) as *a price at which buyers and sellers with a reasonable knowledge of pertinent facts and not acting under any compulsion are willing to do business.*

FMV in the Industry:

The clinical research industry refers to fair market value mostly in terms of prices for subject procedures and site services. Sponsors and sites negotiate the price of the services provided by the site for the sponsor's clinical trial, which are then validated as FMV by an executed contract; the "agreement of exchange" as referenced in our previous example of the \$1 cheeseburger.

Although FMV is a term commonly used in the industry, how to calculate FMV is unstandardized and largely ambiguous.

The most common methods to calculate FMV pricing include:

- **Benchmark databases:** Some sites and sponsors utilize third party companies that offer software as a service (SaaS) for FMV pricing. Most of these software provide benchmarked data in various percentiles aggregated from their customer's own data. This data can be analyzed in a multitude of ways, but it is most commonly used at the 50% percentile per clinical procedure given a specific clinical indication, subject population, and site location.

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- Site defined: Some sites may define their own pricing; especially for direct costs and/or overhead costs. These costs may be based on a division of payments per various internal departments or outsourced services. This method is most commonly utilized by large, academia affiliated sites.
- Historical costs: Some sites and sponsors may create and reference their own databases based on previous work. This data could be analyzed and used in the same ways as the companies that provided SaaS.

Improving the System:

Although there is no classified wrong or right method, each method can yield different pricing ranges which is why consistency and transparency are important factors in negotiations by both site and sponsor.

- Consistency: defined policies and practices of determining FMV pricing that are applied throughout an organization
- Transparency: documentation supporting policies and practices which make them defensible in a negotiation

There are also several federally mandated laws that help force transparency across the industry. However, without these two factors, variances in pricing can easily get compounded as sites and sponsors increase their workload allowing for skewed budgets which in return effect FMV.

Bottom Line:

What sites (sellers) and sponsors (buyers) negotiate in budgets effect the entire industry. The best impact each party can have on the industry is applying consistency and transparency from beginning to end of negotiations. Do your part and contribute to the industry by researching some of the federal laws: Physician Payments Sunshine Act, Federal Anti-Kickback Statute, Stark Law- to name a few.

References:

<https://www.merriam-webster.com/dictionary/fair%20market%20value>

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