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FMV and the Market Failure in Clinical Research

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The market for clinical research site services is broken. Sponsors can't find good sites. Sites can't find good studies. Sponsors complain that sites don't deliver promised services. Sites complain they are paid too little, too late.

In a normal market, supply and demand equilibrate over time:

- If there is a supply shortage (demand surplus), suppliers increase prices, expand production, or turn away orders that are unprofitable or otherwise unattractive. New suppliers enter the market. Customers find new suppliers (which might be higher-priced, less reliable, etc.), reduce their purchases, or accept higher prices or other terms favorable to suppliers.
- If there is a supply surplus (demand shortage), suppliers compete to reduce prices, increase efficiency, improve their product's quality or delivery time, accept less attractive orders, offer terms favorable to customers, reduce production, or leave the market. Customers can increase their purchases and negotiate lower prices and other terms.

The time it takes a market to equilibrate is determined by its elasticities. If supply is elastic, it can change quickly, as suppliers enter and leave the market and make other adjustments. If demand is elastic, it too can change quickly, as customers enter and leave the market and make other adjustments. If pricing is elastic, it too can change quickly, efficiently communicating to customers and suppliers that they have to do something. However, if supply, demand or prices are inelastic, markets break down. This is the case in the market for clinical research site services, where most sponsors perceive a supply shortage while most sites perceive a demand shortage.

The Supply Side

The supply side of the market for clinical research site services is inelastic for several reasons:

- **Suppliers are willing to stay in a market and underprice their services because doing so provides other benefits.** A community hospital might conduct clinical research so it can advertise that it provides cutting-edge medical care. A private-practice investigator might conduct clinical research because he or she enjoys it or any number of other reasons. An academic medical center might conduct clinical research to support the publication needs of its faculty. And, of course, they all might conduct clinical research to benefit the public. These other benefits lead to research sites accepting studies that do not, on a stand-alone basis, make financial sense.
- **Suppliers are willing to stay in a market and underprice their services because they don't realize it is unprofitable.** A site might not appreciate the amount of time that clinical research consumes. Or, they might not fully allocate indirect costs (overhead) to clinical research. Given the stringent eligibility requirements and complexity of many studies, and the low enrollment numbers for a given study (e.g., five subjects), predicting revenue and costs for a given study can be very difficult. And, of course, new sites have very little appreciation for the work involved in clinical research.

- **Suppliers are willing to stay in a market and underprice their services because the alternative is unappealing.** If a site has fixed costs to cover, even an unprofitable study can cover some of those costs. It can take a long time for an established site to admit that market conditions are not improving and it's time to pull the plug, lay off valued employees, and admit defeat.
- **Suppliers are unwilling to adjust their prices, leaving aside what customers are willing to pay.** In clinical research, "standard of care" pricing plays far too large a role. Just as pricing varies for clinical care based on the local market, therapeutic area, the cost of delivery, and the payor (patient, insurer or government), it can also vary by study, study sponsor, or current market conditions, provided any differences are justifiable under the anti-kickback and Stark laws.
- **Suppliers are slow to increase efficiency.** Clinical research is a labor-intensive business. Technology can help, but it is too costly and time-consuming to implement for many sites. (However, there is reason for hope.) Too often, gains in efficiency by sites are overwhelmed by losses in efficiency due to increasingly complex study designs, more stringent eligibility criteria, and technologies designed to increase *sponsor* efficiencies.

The Demand Side

The demand side of the clinical research site services market is also inelastic for several reasons:

- **Customers cannot adjust their demand easily.** Because clinical research is so costly, study sponsors already look very closely at the number, size and design of their studies. Studies have to be performed in order. Delaying them for budgetary reasons is a last resort once a clinical development program is underway.
- **Customers do not vary pricing based on the quality of the product or service provided.** Study sponsors tend to pay all sites the same prices, within narrow ranges. (Commercial study budget databases contribute to this problem because they look only at signed contracts, not at the volume or quality of the services actually provided.)
- **Customers overestimate supply.** Clinical trial enrollment forecasts are notoriously over-optimistic because study sponsors often underestimate the ability of their sites to enroll and retain study subjects. In other words, study sponsors overestimate the supply available in the market. More realistic estimates would cause study sponsors to understand the realities of the market and adapt accordingly.

Other Contributors

On both sides of the market, a lack of knowledge creates inelasticity:

- Sponsors do not know which sites are best for each study, especially since there are so many sites, site personnel often change, site capacity can vary dramatically over time, and site performance can vary from study to study for inexplicable reasons. (However, there is reason for hope.)
- Sites do not know which sponsors are looking for sites for which studies. Sites can hire business development personnel or services to obtain this information, but it is an expensive process that is unlikely to generate comprehensive and detailed information.
- Neither sponsors nor sites seem to understand the other's needs. For example, sponsors do not appreciate the impact of slow payment on sites with marginal profitability and irregular revenue. Sites do not appear to appreciate the impact of

under-enrollment on sponsors under tremendous pressure to bring a new product to market.

One area in which the market for clinical research services is very elastic is the entry of new suppliers into the market; there appears to be an inexhaustible supply of physicians willing to give clinical research a try. However, during their typically short tenure in the market, their acceptance of low prices while learning about the challenges of conducting profitable (and satisfying) clinical research leads them to exit the market as quickly as they entered it, meanwhile diverting resources from study sponsors. The supply of capable sites is far less elastic, although the number of departures appears to have increased over the past few years.

Solutions

Most solutions to the clinical research site services market failure are well known:

- Sponsors should improve their ability to learn about sites, and sites should improve their ability to learn about sponsors and their studies.
- Sponsors and sites should improve their ability to assess study feasibility.
- Sponsors should improve their ability to select sites and predict enrollment.
- Sponsors should give more consideration to the impact of new technologies on sites.
- Sponsors should help strong new investigators succeed and redirect the others to become subinvestigators or sources of patient referrals.

Two solutions are less well known:

- Sites should improve their ability to measure their clinical research costs.
- Sites should assess, in financial terms, the other benefits they obtain by conducting clinical research.

Most of these solutions involve increasing information, which is always good for markets. With more information, buyers and sellers can make better business decisions, which increases market elasticity because it speeds up the process of the strongest competitors expanding and the weakest changing their business strategy, leaving the market, or being acquired. However, some of these solutions are difficult in practice. It is no accident that these solutions are solving 20-year-old problems.

Pricing: The Forgotten Solution

One solution, however, is relatively easy to implement and it's the most important: variable pricing. Although some strong sites price their services based on the *value* they deliver, most of the market is governed by commodity — one size fits all — pricing (within a narrow range). Suppliers that deliver high value to customers should be able to price their services based on that value. Similarly, suppliers that can deliver their services more efficiently can gain market share with lower prices. Commodity pricing interferes with these strategies.

Pricing is a core function of markets and the key to market elasticity. Prices are how customers and suppliers communicate value. When customers pay higher prices, they communicate to suppliers that they should increase production, using the additional revenue from the higher prices. When customers pay lower prices, they communicate to suppliers that they should decrease production, improve the value of their products, sell different products, become more efficient, or leave the market.

Customers also compete among themselves with pricing. Study sponsors with the most important products should be able to pay the strongest research sites for the value of their services and complete their studies faster. There is no legal prohibition against study

sponsors or sites varying prices paid based on the local market, therapeutic area, the cost of delivery, and, most importantly, the quality, timeliness and reliability of the services provided. With the data produced by risk-based monitoring, it is easy for sponsors to justify paying higher prices to sites that require less monitoring, especially if a site has invested in a costly quality assurance program.

Fair Market Value

There are four pertinent laws: the Stark law, the anti-kickback law, the False Claims Act (FCA), and the Foreign Corrupt Practices Act (FCPA). The FCA applies to clinical trials and research in a variety of ways, including, but not limited to, billing Medicare for services that the sponsor is obligated to pay. (States have similar laws.) The anti-bribery provisions of the FCPA apply to all U.S. companies and persons, and to foreign companies and individuals who work on behalf of U.S. individuals and companies if the foreign company qualifies as an "Issuer" of securities registered under the Securities Exchange Commission. All of these laws require that payments be consistent with "fair market value" (FMV).

FMV is the price of a product or service commonly paid by a buyer to a seller in an arm's length transaction. Prices should be consistent when like sellers provide like products to like buyers. The more diverse the market, the greater the range of FMV or, from a different perspective, diversity creates multiple markets, each with its own FMV.

To determine FMV, a buyer or seller must first define the market in which it competes. At one extreme, the market for some products and services, such as U.S. government bonds, are global, with essentially identical pricing everywhere. At the other extreme, if there is one hospital in the world that can perform a particular procedure, that hospital comprises the entire market. Between the two extremes, defining a market can get very complicated because competition is measured in degrees. In the market for clinical research services, the location and type of a site are important factors to consider.

The buyer or seller must then determine the prices in its market. Databases are available with comprehensive price data for clinical research site services, although the information is expensive. In the absence of such data, study sponsors and sites must determine FMV the best they can with the data they have.

The buyer or seller must then set its own "standard" prices and test them in the market. Study sponsors might set their standard prices above or below average prices in their market. For example, financial constraints might require below-market pricing, while "getting the best sites" might require above-market pricing. The same freedom applies to sites. However, high prices, e.g., those in the top quartile, might catch a regulator's suspicion. Ultimately, the market should determine the *right* prices.

With standard pricing in hand, the buyer or seller can then create a pricing plan that varies based on the characteristics of the party on the other side of the table.

To minimize legal risks, the buyer or seller should:

- State its pricing plan in detail.
- Explain its policies for determining its market, setting its standard prices, and adjusting prices based on circumstances.
- Apply its pricing policies consistently.
- Be prepared to justify high prices, whether or not they are consistent.
- Document its rationale for variations from the standard prices in specific cases.

Some study sponsors have adopted the policy of classifying research sites into tiers based on factors like expertise, data quality, reliability and location…but not prescribing volume. Sites can obtain higher prices by demonstrating that they belong in a higher tier.

Deviations from FMV must be based on legitimate commercial reasons. To start with, a price range of perhaps +/-10% is probably acceptable. Outside that range, prices can be based on local market conditions, the quality of the data, the reliability of the site, the prominence of the investigator, and a host of other factors. A pharmaceutical company is not allowed to induce a site to prescribe its products by paying it more than FMV for conducting a clinical trial. However, it can pay a site more that it pays other sites if, for example, that site has proven that it can deliver high-quality data on schedule, with minimal site monitoring.

While the various laws target prices that are above FMV, there are also cases in which prices are below FMV. These too, can be legitimate if they are based on a reasonable commercial rationale. For example, sponsors can justify paying lower prices to inexperienced sites because of the risk the sponsor incurs. Similarly, sites may be able to justify charging low, introductory prices to new customers or low, repeat business prices to existing customers. However, the remaining prices are now "high" prices and must be justified.

There is no requirement that the price of a procedure in a clinical study must be the same as the price of the same procedure in clinical care. In fact, the extensive documentation and other associated costs in clinical research can justify a higher price. Nevertheless, many sites charge study sponsors less than they charge insurers for clinical care costs.

Bonuses for rapid subject enrollment are ethically problematic because sites might coerce patients to enroll or enroll ineligible patients to earn the bonuses. Study sponsors and sites must balance such ethical considerations against the value provided by sites that quickly enroll high numbers of subjects.

Whatever the reasons for variable pricing, to protect against legal sanctions, study sponsors and sites should document their pricing policies, apply them consistently, and record their rationale for each study.

Conclusion

The market for clinical research site services is broken. Sponsors can't find good sites. Sites can't find good studies. Sponsors complain that sites don't deliver promised services. Sites complain they are paid too little, too late. These problems can be solved by increasing market elasticity, especially by freeing prices to vary based on quality, delivery and other factors important to study sponsors. By paying attention to the fundamental characteristics of markets, we can create a rational market in which suppliers deliver high-quality services to customers on schedule and for a fair price.

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