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Streamlining Study Startups with Master Price Lists

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Study budget negotiations can be one of the most time-consuming activities in starting up a clinical study. It can also be a source of tension as the negotiating parties seek common ground between the sponsor's budget template and the site's chargemaster.[1] Even when the budget from a previous study can be referenced, it can often seem like the negotiations are starting from scratch, since circumstances and negotiators may have changed in the interim and the rationale for the previous study budget may have been forgotten.

Master clinical trial agreements (mCTAs) were invented years ago to streamline the process of negotiating the legal terms.[2] More recently, sponsors and sites have begun negotiating master price lists (also known as MPLs or master clinical trial budgets) to establish standard pricing between a sponsor and a clinical trial site for a list of anticipated activities, procedures and fees. Once an MPL is in place, the negotiation duration and labor costs can be greatly reduced.

Master budgets should include assessments, procedures and other activities that are likely to appear in future study budgets. To avoid misunderstandings, these items should be specified with a Current Procedural Terminology (CPT) code or an unambiguous text description.

The clinical care chargemasters of different departments in a hospital or different facilities in a healthcare system may specify different prices for the same assessments and procedures. Clinical research chargemasters are often based on these prices, complicating negotiations with study sponsors. Therefore, to the extent possible, sites should create a single, uniform price list for an MPL. If that is not possible, a simple percentage adjustment across departments or facilities is preferable to multiple price lists.

Study sponsors may have their own study price lists that vary across clinical development programs, therapeutic areas, or subsidiaries. To the extent possible, these price lists should be consolidated.

Is a Master Price List Right for You?

Master price lists are especially useful when a sponsor that has multiple budget negotiation centers conducts a variety of studies across a site that has multiple departments or facilities. The challenge, of course, is that it becomes exponentially more difficult to conduct multilateral discussions that involve all of these diverse parties who, presumably, designed their unique price lists for some reason. Each side should, therefore, empower a single negotiator to represent the entire organization, backed up by representatives from the affected organizational units.

There is no need to include every chargeable item, department, business unit, therapeutic area, and study type in an MPL. To the contrary, an initial MPL with a limited scope will be easier to negotiate. Once the parties gain confidence in it, its scope can be expanded.

If a sponsor just conducts a series of similar studies at a given site, they may already have a de facto MPL that does not need to be formalized.

An MPL is more likely to be a useful tool if the following considerations apply:

- The study sponsor and the research site already have a strong relationship.
- The study sponsor and the research site expect to conduct enough diverse studies together to justify the investment in an MPL.
- The study sponsor and the research site find the process of negotiating regular study budgets with each other relatively straightforward.
- The study sponsor and the research site are already using an mCTA.
- The two parties have the organizational wherewithal to negotiate an MPL.
- The two parties have the stability to benefit from an MPL for a few years.

Other Content

In addition to a standard price list, MPLs can also include terms and conditions to govern their usage. For example, they may include clauses, such as the following:

- A statement of scope, which might, for example, specify therapeutic areas
- The procedure for negotiating prices not included in the MPL
- A list of activities or fees, if any, that will not be charged
- An inflation clause to adjust prices when a price index (typically the Consumer Price Index for Medical Care Services) increases
- Conditions under which a party can request price adjustments for a specific study or to the MPL as a whole (e.g., if a subcontractor increases its prices)
- The term of the agreement (often three years, to make the negotiation worthwhile)
- Termination provision, (e.g., upon notice and completion of open studies)
- Other typical contract language, such as parties to the agreement, force majeure, and notification, that are not covered in the mCTA or individual CTAs.

Implications for CROs

When a study sponsor is looking for a CRO to manage a study, the request for proposal (RFP) or request for quotation (RFQ) must specify that the sponsor's existing MPL will be used, even if the CRO believes it can negotiate lower prices with those sites. The CRO's fees for negotiating budgets should be reduced appropriately.

Master Price Lists and Fair Market Value

Fair market value rules apply to MPLs. The prices in MPLs with like partners in similar arrangements should be consistent. Reasonable deviations from the prices in regular study budgets can be justified based on the long-term, high-volume nature of the relationship.

Conclusion

Master price lists can improve the speed and efficiency of study startups for sponsors and sites in a continuing relationship. Such relationships are becoming more and more important for the future of clinical research.

References

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