

An Executive Summary

GrantPlan: Making Fair Market Value a Reality



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Benchmarking a clinical trial in an accurate way depends on a large data set that is continually updated.

Overview

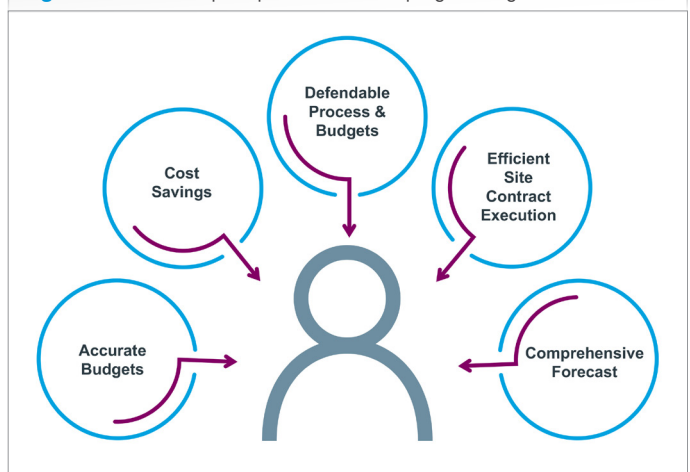
Building an accurate budget for a clinical trial comes with a host of challenges. These include, but are not limited to, intricate protocols, large enrollments, shortened timelines and global sites. By using IQVIA Technologies' GrantPlan—a benchmarking tool that uses a global dataset—experts can develop fair market value (FMV) costs. Furthermore, costs can even be associated with the disease indication being studied, which is particularly useful in negotiating costs for investigators. GrantPlan is used by more than three-quarters of the studies currently submitted on *clinicaltrials.gov*. This webcast summary reviews the top features of GrantPlan.

Points of Pain

When developing a budget for a clinical trial, even experts run into common pain points, as shown in **Figure 1**. One such challenge is building an accurate budget. This is crucial because the budget must be approved by the clinical team at various trial sites. To “smooth” any negotiations, the budget must be as accurate as possible and follow the schedule of assessment in the protocol.

The process and the budget must also be defensible. This requires having a tool such as GrantPlan to ensure that all costs are FMV and lie within the benchmarks. Additionally, the plan must provide a comprehensive forecast. Numerous sponsors and CROs are reliant on their historical data, which are valuable to understand benchmarks. However, the data may not be current depending on

Figure 1: Common pain points of developing a budget.



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Figure 2: Power of the data.

Code	Procedure	Study Qty	Sponsor	SoC Qty	OH	Initial Offer	Upper Limit	IQV	Industry Benchmarks			
						Cost	Cost	Med	Low	Med	High	Src
1	INCON	1	1	0	✓	131	131	83	115	131	157	A
2	99205	1	0	1	✓	276	0	233	260	276	277	A
3	99211	11	8	3	✓	52	416	n/a	48	52	56	A
4	36415	11	8	3	✓	46	368	43	344	43	46	A
5	S9818	12	12	0	✓	23	276	27	20	23	27	PL
6	31654	1	1	0	✓	258	258	179	258	258	372	PL
7	93000	1	0	1	✓	138	0	120	136	138	152	A
8	67028	1	0	1	✓	500	0	n/a	385	500	650	PL
Procedure Sub Total Before SoC Applied:						US\$2,657	US\$2,638	US\$1,134	US\$2,316	US\$2,657	US\$3,087	
SoC Savings Sub Total:						US\$1,208	US\$1,208	US\$465	US\$1,054	US\$1,208	US\$1,394	
Procedures Sub Total:						US\$1,449	US\$1,430	US\$679	US\$1,262	US\$1,449	US\$1,693	

when it was generated, which results in a lack consistency with FMV.

Ultimately, what sets GrantPlan's FMV apart is the use of data that are less than two years old. Information on a procedure or cost must come from at least three different sources and include five different data points to be considered an 'actual', which reinforces confidence in budgeting. If such criteria are not met, the information gathered is used in addition to an algorithm to ensure that the user always has a nominal cost associated with their specific request. Other tools lack the "power of three and five" and use data that are more than three years old, leading to costs that are dictated by the market.

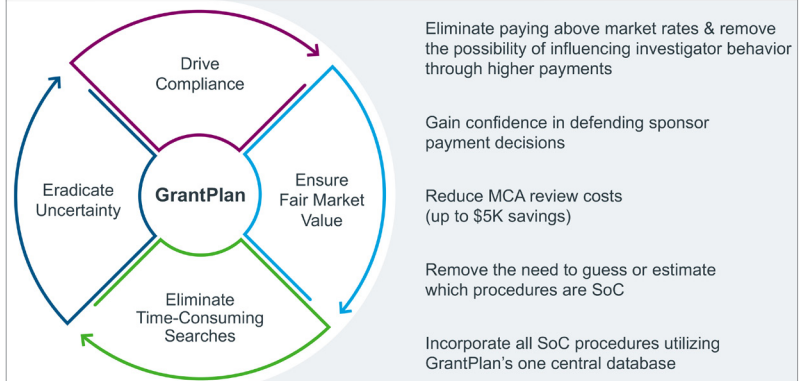
Benefits of Breadth

The information used to develop actual benchmarks varies between tools. For example, some tools include many zeros and N/As, which reduce the value of the information. With no zeros or N/As in GrantPlan, users can be confident in the robustness of the information, which spawns smoother negotiations.

On *clinicaltrials.gov*, 76% of the trials use GrantPlan, which creates a large amount of data. At the time of this summary, this online resource listed about 315,000 clinical trials, which means that over 225,000 were using GrantPlan.

The resulting amount of data—including the costs of a wide range of procedures in many countries—makes GrantPlan

Figure 3: The advantages of GrantPlan.



inclusive. Other tools often require collecting information from outside sources, including the Internet, which leads to delays such as finding some costs and vetting them with a group's clinical team. Plus, those added steps can fuel longer and often more complicated negotiations.

Power of the Data

GrantPlan includes a price breakdown, as shown in Figure 2. GrantPlan provides a collection of information: industry benchmark prices that are low, medium and high, sources of the information, and so on. More importantly, it records a company's historical data to provide users their company Medium in its own column, shown in Figure 2 as "IQV".

The tool has the capability to denote procedures that will be Standard of Care (SoC) as well as the quantity with

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Multi-Country Coverage

As previously mentioned, GrantPlan includes data from many countries. To be more specific, those data come from more than 60 countries, where the data can be used to build the budget for a clinical trial. As a result, GrantPlan supplies costing and a robust amount of data for those 60 countries.

What if a team wants to build the budget for a trial in a country that is not part of the top 60? For such cases, GrantPlan includes 130 additional countries or country equivalents. A user simply picks a country, and if many studies have not been carried out in that country, then data on a source country—an equivalent country—will be provided.

For instance, not many studies have been run in Bangladesh, so India is used as the source country for Bangladesh. Then a user can view the source country, the source currency, the local currency, and the planning currency—all provided automatically so that the user does not need to go outside of the system. Consequently,

a simple click of a button. GrantPlan then applies the allocation to a specific timepoint based on several study factors and designated visits with the ability to modify the allocations, if deemed necessary (Figure 3). For example, anyone can see the SoC included in a trial. This eliminates haphazard choices at trial sites.

Figure 4 shows that GrantPlan Standard of Care compares the line items in a budget with the more-than-one billion U.S. medical claims, which account for 70% of all reimbursed care. The line graph shows the range of saving in Phase-III studies for four therapeutic areas: oncology, central nervous system (CNS), cardiology, and respiratory. The range in savings varies by therapeutic area: for example, 23–34% and 17–22% for oncology and respiratory, respectively. This reveals money that can be allocated to a different trial or even a different program.

Figure 4: GrantPlan Standard of Care maps the U.S. Medical Claims data against the line items in the budget.

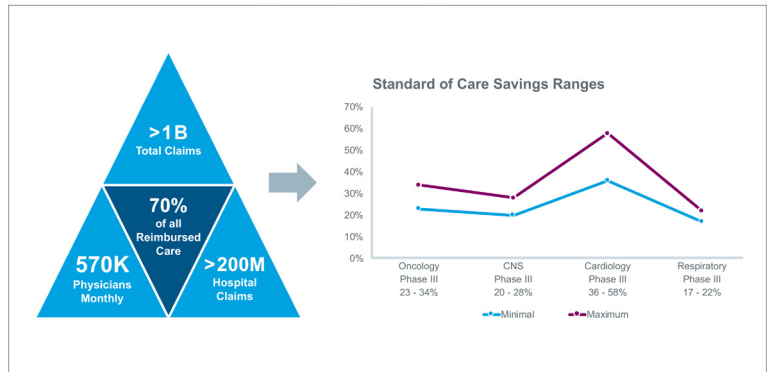
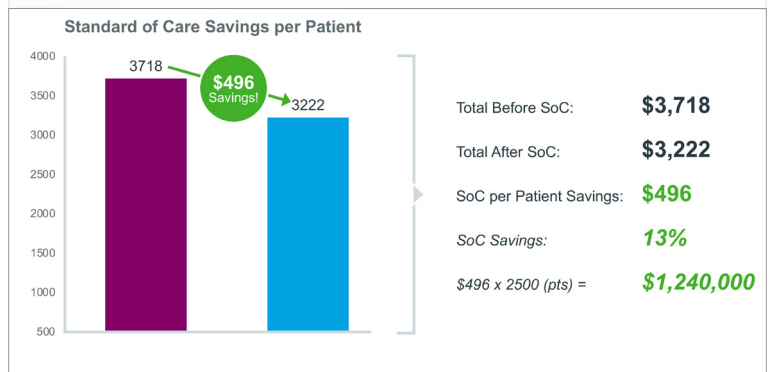


Figure 5 depicts a 22-month-long, hypothetical inflammation study that includes seven visits and 10 overall procedures—three of which are SoC procedures. Before SoC, the cost would be \$3718; after SoC, the cost would be \$3222, which produces a savings of \$496, 13% savings, for each patient. If the study includes 2500 subjects, that per-patient savings grows to a total of \$1,240,000.

Figure 5: Return on investment of a 22-month inflammation study, including 7 visits, 10 procedures, and 3 Standard-of-Care (SoC) procedures.



Such savings are ideal, and the fact that GrantPlan includes the information and data required to accurately forecast such savings improves the team’s comfortability and confidence that the number is accurate.

“GrantPlan enables users to build a clinical-trial budget based on robust data.”

a user can develop costing for a study in Bangladesh based on costs in India, and GrantPlan converts the rates as needed to build a budget for sites in Bangladesh.

If a budget needs to be adjusted at a later time—even a few years later—GrantPlan can handle changes in exchange rates that are updated monthly. However, it does not automatically make that adjustment. If someone is copying a study when making an amendment, the initial costing might want to be kept, which means that the exchange rates would not need to be updated. Changes could be made in the amendment such as in visits or procedures, but the rest would stay the same.

On the other hand, the exchange rates need to be updated in some situations. For example, if someone wants to build a budget for a sister study a year after the first one—but keeps all of the visits, procedures, and so on the same—the study can be copied, the exchange rates updated and the new budget is ready to go.

Accounting for Complexity

GrantPlan also includes a complexity factor that builds in some adjustability in costs. For example, all patient visits are not the same at all sites, and a site might request more money because of a higher patient burden such as a 12-hour visit.

GrantPlan’s complexity factor arises from multiple parameters, such as the number of visits, the number of subjects, and the study population. From that, this tool calculates the cost-increase percentage that such complexities could cause. But the team building the budget decides if and when that percentage gets added. For example, it could be added at a per-patient level; in that case, it would be added to the total cost per patient.

The complexity factor could also be applied at the visit level to specific kinds of visits. For instance, the complexity factor might be added to visits that require a long day or multiple invasive procedures, such as tumor biopsies or multiple scans. The team building the budget decides when and if to apply the complexity factor. The key is that the complexity factor takes away subjectivity in building the budget.

The complexity factor can also be added to the budget cap. That provides a cushion in a budget. So, instead of renegotiating every overage, the cushion can be used. This method of using the complexity factor can clearly save time during a trial by reducing the need to confirm on every cost overrun, but it can also speed up budget building.

Like other features in GrantPlan, the team building the budget decides how or if it will use the available features. As indicated in the example of exchange rates, they can be kept as they are or updated accordingly. Similarly, a budget-building team can use the complexity factor or not. The complexity factor can even be used in some places, such as per-patient costs but in not others, such as the visit level.

Conclusion

GrantPlan enables users to build a clinical-trial budget based on robust data. Consequently, a team builds a budget with confidence in the projected costs, keeping them at FMV, which results in simplified negotiations. GrantPlan streamlines the budget-building process and removes much of the guesswork regardless of site location.

In addition, the team creating the budget determines where to use features and how while working with a tool that makes it easier than ever to build the most reliable budget and adjust it as needed.

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