

Cost Inflation in Clinical Research

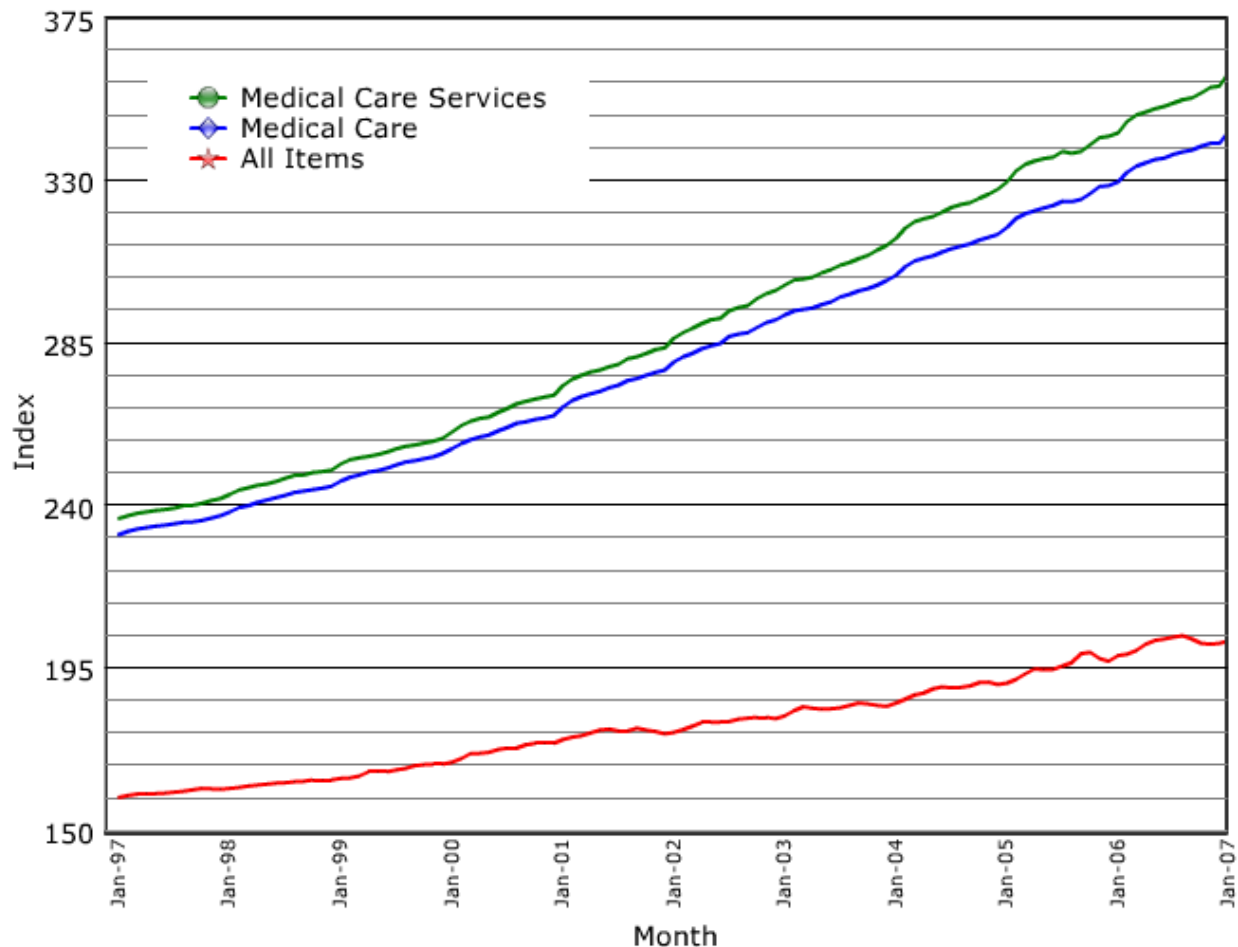
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The U.S. Department of Labor Bureau of Labor Statistics publishes monthly price indexes that can be used to adjust clinical research budgets for the effects of inflation.¹ The chart below shows that in the ten-year period from 1997 through 2006:

- The index for all items increased an average rate of 2.4% per year.
- The index for medical care increased an average rate of 4.0% per year.
- The index for medical care services increased an average rate of 4.4% per year.

The medical care services index is probably the most accurate for the services provided by a clinical research site to a sponsor. A cost increase of 4.4% per year can significantly impact the narrow profit margins of most clinical research sites.

U.S. Consumer Price Index
(U.S. City Average, Not Seasonally Adjusted)



Using the Consumer Price Index in Contract Escalation Clauses

The U.S. Department of Labor Bureau of Labor Statistics provides the following guidelines for using its consumer prices indexes in contract escalation clauses:

- DEFINE clearly the base payment (rent, wage rate, alimony, child support, or other value) that is subject to escalation.
- IDENTIFY precisely which CPI index series will be used to escalate the base payment. This should include: The population coverage (CPI-U or CPI-W), area coverage (U.S. City Average, West Region, Chicago, etc.), series title (all items, rent of primary residence, etc.), and index base period (1982-84=100).
- SPECIFY a reference period from which changes in the CPI will be measured. This is usually a single month (the CPI does not correspond to a specific day or week of the month) or an annual average. There is about a 2-week lag from the reference month to the date on which the index is released (e.g., the CPI for May is released in mid-June). The CPI's for most metropolitan areas are not published as frequently as are the data for the U.S. City Average and the 4 regions. Indexes for the U.S. City Average, the 4 regions, 3 city-size classes, 10 region-by-size classes, and 3 major metropolitan areas (Chicago, Los Angeles, and New York) are published monthly. Indexes for the remaining 23 published metropolitan areas are available only on a bimonthly or semiannual basis. Contact the BLS address at the end of this fact sheet for information on the frequency of publication for the 26 metropolitan areas.
- STATE the frequency of adjustment. Adjustments are usually made at fixed time intervals, such as quarterly, semiannually, or most often, annually.
- DETERMINE the formula for the adjustment calculation. Usually the change in payments is directly proportional to the percent change in the CPI index between two specified time periods. Consider whether to make an allowance for a "cap" that places an upper limit to the increase in wages, rents, etc., or a "floor" that promises a minimum increase regardless of the percent change (up or down) in the CPI.
- PROVIDE a built-in method for handling situations that may arise because of major CPI revisions or changes in the CPI index base period. The Bureau always provides timely notification of upcoming revisions or changes in the index base.²

Clinical Trial Agreement Language

Anticipated cost increases can be factored into fixed-price budgets for clinical trials lasting less than a year or two. For longer trials, the following language can be used for a simple price escalation clause in clinical trial agreements:

The Budget will not change during the initial {1/2/3} year period after execution of this Agreement. If the Study is not completed by the end of that period, Sponsor will adjust compensation to Site at that time for the following year and annually thereafter based on actual third-party charges and, in the U.S., on the increase in the U.S. City Average Medical Care Services Consumer Price Index from the month this Agreement became effective to the date of the adjustment.³

Study sponsors may not take the initiative on price escalation clauses. Nevertheless, site costs will probably increase over the course of a long trial.

References

1. <http://www.bls.gov/cpi/#tables>
2. <http://www.bls.gov/cpi/cpi1998d.htm>
3. MAGI Model Clinical Trial Agreement (<http://www.firstclinical.com/magi>)

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