Compensation to Human Clinical Study Participants: A (Very) Informal Survey

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At least once a month, life science clients reach out to us to ask us about best practices on a particular topic or to benchmark a proposed activity against what others in the industry might be doing. One such request, concerning compensation to clinical trial subjects, came up recently that we thought we would share. While our informal survey is not scientifically sound, it offers some insight as to norms.

Specifically, we reached out to a number of pharmaceutical companies to inquire about compensation for clinical trial participants.

Our questions were, with regard to Phase II and Phase III trials:

1. Does the company provide compensation, beyond reimbursement for transportation, accommodations and meals, to clinical trial subjects for participation time?
2. If yes, how is the payment structured (e.g., a flat or hourly rate)?
3. How much is the payment amount?

Of the respondents, almost half of the companies offer nothing more than reimbursement for incurred expenses. The remaining small majority offer compensation for time, discomfort or inconvenience.

Where the study is particularly burdensome for the clinical trial subjects (e.g., involves painful or invasive services) or requires a substantial time commitment (e.g., multiple or lengthy visits are needed), some companies compensate for participation time. In such cases, reimbursement typically will be a flat fee and generally paid per day of participation (that is, when a visit or other contact is required). The daily flat rates typically range from $50 - $150, with a couple of outliers ($250, $350). Companies reported that the amount was based on the procedures performed, the number of assessments, and length of visit (e.g., overnight stay versus outpatient visit). Companies were cognizant to comply with applicable healthcare compliance laws; the amount paid was carefully structured so it would not be considered an inducement.

While we did not specifically ask (as our interest was more on later-stage trials), two companies responded proactively that, for Phase I trials, where healthy patients are involved, they compensate for participation, often at a rate as high as $2,000 per study.

AGG Observations

The informal results are interesting in that there is no black and white answer or consensus. All companies seem to pay out-of-pocket expenses, but others may pay for more. The structure of payment may vary depending on factual circumstances of the study (e.g., time), as do the specific payment amounts. However, in all cases, the respondents noted that the decision whether to compensate and the structure is vetted to ensure regulatory compliance. In all cases, each company had a policy (some more formal than others) that was reviewed and approved internally, as well as documented. Company stakeholders carefully considered business objectives, while also recognizing legal boundaries. There is a rhyme and reason for everything.

At the end of the day, each company will make its own decision, but such benchmarking exercises help identify the rules of the sandbox where their colleagues are playing and provide guidance on parameters to set to balance corporate goals and legal compliance.

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