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Longer Trial Durations For Large Molecule Clinical Trials: Results From KMR Group's Annual Cycle Time Report

CHICAGO, Illinois, October 27, 2016 – KMR Group, a leader in analyzing R&D performance data for the biopharmaceutical industry, recently conducted its annual Clinical Trial Cycle Time Report. Results of the analysis show the duration of clinical trials associated with large molecule drugs take significantly longer than trials associated with small molecule drugs.

KMR Group's 2016 Clinical Trial Cycle Time Report evaluated cycle time performance for over 17,000 interventional trials across all therapeutic areas, from trials conducted between 2005-2015. As with all of their analyses, the performance data is collected directly from sponsor biopharmaceutical companies and CROs.

A myriad of factors were analyzed, e.g., outsourcing, disease complexity, study size, subject type. One of the key findings was that even after accounting for disease complexity and study size, large molecule trials are consistently longer at a statistically significant level. This finding holds across phases, where large molecule trials tend to take longer in Phase I healthy volunteer studies as well as Phase II and III studies. As an example, for Phase III oncology trials the total duration for small molecules is a median 4.5 years compared to 6.1 years for large molecules.

The report found there is not just one particular process driving these results. Rather most processes are longer for large molecule trials (e.g., study startup, enrollment, data capture) in addition to lower recruitment rates. When accounting for discrepancies in trial size by looking at the recruitment rates, it is evident that large molecule trials recruit at a lower rate. Small molecule studies recruit a median 17.5 subjects per month in Phase III for oncology, compared to 14.2 subjects per month for large.

“Given the complexity and challenges associated with large molecules, it is not surprising there is variance. However understanding where the differences reside operationally, as well as the extent of the gaps and what influences them, can be critical to improving operational performance,” commented Linda Martin, President and Founder of KMR Group

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About KMR

KMR Group has worked exclusively in biopharmaceutical R&D since the early 1990s. KMR Group is an industry leader in benchmarking, analytics and performance management as well as a developer of on-line analytics tools that enable access to our propriety and rich datasets. KMR's clinical platform contains the most reliable source for trial performance, recruitment and site metrics data, with over 25,000 global clinical



trials. Clients rely on these tools to benchmark performance, define recruitment strategies and shape enrollment plans and to identify best performing sites. For more information or for a demonstration of any of KMR's tools, please contact us.

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