



## 2018 KMR Group Biosimilar Performance Assessment Study

This month **KMR Group** completed a detailed industry benchmarking assessment on biosimilar drug development.

Given the extraordinary pressure to be the first to market – which is especially acute for biosimilars – the study concentrated on cycle time.

**It found that the overall length of biosimilar trials is generally similar to that of non-biosimilar trials for the same disease area but that the biosimilar trials are substantially larger.**

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The assessment emphasized three main areas: **Biosimilar Product Development, Biosimilar Trial Design, and Biosimilar Trial Performance**. Data was normalized by disease and phase when assessing trial performance and comparing biosimilars to biologics products. Some of the factors analyzed:

**Biosimilar Product Development:** Originator batches analyzed, screened clones included in initial product quality assessments, number of formulations developed

**Biosimilar Trial Design:** Trial size, phase, disease, treatment duration, geography

**Biosimilar Trial Performance:** Total trial duration, study start-up, enrollment rates, data capture, statistical analysis & reporting cycle times

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The study was based on a careful analysis of clinical development data that was provided directly from a group of major sponsor companies. Data was extensively queried to ensure accuracy and comparability across participants.

### **Among the key findings:**

Biosimilar trials in Phase I and III have similar Total Trial Durations compared to biologics trials.

In Phase III, biosimilar trials enrolled 28% more subjects, when compared to non-biosimilar trials for the same disease.

Biosimilar trials also tended to have longer start-up and statistical analysis cycle times than non-biosimilar trials.

Biosimilar trials generally have shorter reporting processes.

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To evaluate your company's biosimilar drug development performance and have reliable benchmarks on biosimilar product and trial design, contact us for more information. We will work with your company to evaluate how you fit into the current landscape, explore how your internal processes are impacting performance, and highlight operational and strategic levers to drive better performance.

### **About KMR Group**

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 propriety and rich datasets. KMR's clinical platform contains the most reliable source for trial performance, recruitment and site metrics data, with nearly 30,000 global clinical trials. Clients depend on these tools to benchmark performance, define recruitment strategies and shape enrollment plans and to identify best performing sites.

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### **For more information on the Biosimilar Benchmarking Study contact:**

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