
# DSG Builds CAR T Study for Blockbuster Drug Granted Breakthrough Therapy Designation for Multiple Myeloma

**Summary:**

DSG was approached by a pharmaceutical sponsor with the request to provide EDC, IRT, Data Management and Biostatistics for a 2-part, multi-site Phase 1 study in adults with relapsed/refractory multiple myeloma. The sponsor specifically was looking for a team with CAR T experience, and a system that could handle their unique database build with a team that could provide in-house data management and a biostatistical team.

**Sponsor Challenges:**

The sponsor had identified frustrations establishing relationships with vendors that could provide EDC, IRT, in-house data management and a biostatistical team to have one central point of contact. The sponsor expressed concerns regarding build time-lines, data management implementation and a team that could provide biostatistical support. As a result, the sponsor needed a vendor with CAR T experience, and a company that can provide cohesive solutions and services.

**Our Solution:**

The sponsor selected DSG as their preferred vendor for the support of the database build of EDC and IRT, as well as conduct including data management and biostatistics. DSG's solution was to provide an experienced team, all working together to ensure rapid implementation and effective conduct services.

To achieve these outcomes, DSG engaged a team comprised of project managers, data managers and biostatisticians with CAR T and multiple myeloma experience. These domain experts were then coupled with eCaselink implementation specialists who could then take the input from the SMEs and configure the different modules such as EDC and IRT from the eCaselink unified platform in the most optimal manner taking into account the specific design and work-flow needs of the program.

DSG's combination of technology and therapeutic experience allowed the team to efficiently build all the protocol specific eCRF's with minimal revisions and to create study specific reports to monitor various aspects of the study and the sites from the study startup phase itself. The synergy of the study team and the biostatistical team working together from the beginning resulted in providing analytical dashboards for study trends and a plan to execute steps for statistical analysis up front to ensure a fast delivery and early submission.

## The Result:

DSG was able to implement an EDC and IRT system built specifically for CAR T two weeks faster than the proposed timeline, while taking into account all the study needs including custom workflows and real time analytics. The DSG team performed the system build per the needs of the protocol, with necessary validations, reconcilations and compliance checks built in, which enabled the in-house data management team to ultimately ensure excellent data quality and timely database locks. In addition, the biostatistical support and input throughout the conduct of the trial resulted in an early submission. DSG accommodated each study change and protocol amendment in stride using the same approach to ensure all groups were focused with the end goal in mind, while keeping the cost at a minimum. This study was ultimately granted Breakthrough Therapy Designation (BTD) from the FDA and prime eligibility from the EMA.


## About DSG:

Founded in 1992, DSG is a leading global eClinical provider with a fully unified suite of innovative technology solutions and data management services for the global clinical research community. Our cloud-based eClinical software platform, eCaseLink™, provides capabilities that deliver operationally efficient results that are cost-effective. DSG's solutions have been used in thousands of clinical trials leading to approvals by global regulatory authorities such as the FDA, EMA, MHLW and CFDA.

### *Our Mission:*

*Innovate today to provide valuable solutions for tomorrow.*

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