

MCRA Helps Rescue a Clinical Study That Previous CRO Mismanaged

Client Need

ACell, Inc. is a leading regenerative medicine company focused on the development, manufacturing, and commercialization of medical devices for wound management and surgical soft tissue repair.

ACell retained MCRA's clinical experts to resolve data integrity issues and close out a study that was previously mismanaged by another CRO.

"ACell engaged MCRA to help rescue a clinical study that a previous CRO has mismanaged. MCRA's team worked with us to solve the data integrity issues and provided guidance on how to appropriately close the study. MCRA's integrated model provides for seamless communication, cohesive clin-reg strategies, as well as the comfort of having ready access to knowledgeable, experienced subject matter experts to overcome roadblocks."

Jim Kuras, VP of Clinical, Search and Development, ACell, Inc.



MCRA Approach

MCRA's integrated teams collaborated closely with the sponsor to create a Protocol Advisory Committee set up to review all endpoint data, AEs and PDs to provide a clean unbiased dataset.

MCRA THERAPY:
Wound Care

MCRA SERVICES:
Clinical

Outcome

Through extensive meetings with field experts and a statistician, MCRA was able to help ACell clean up a study that had several issues and were able to successfully make use of the data.

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