

CASE STUDY PRESENTED BY PREMIER RESEARCH

# Challenging Complexity: A Novel Treatment That Worked So Well It Almost Derailed the Study

We were testing an autologous chondrocyte transplantation system to repair damaged knee cartilage. The problem was that patients felt great after treatment, and saw no need to make follow-up visits.

But the FDA required us to track results for seven years.

The challenge: To keep patients involved for seven long years, especially active young patients who moved away from their original locations.

## The unexpected skills that made the difference

Of course, understanding the science was key. The procedure offered unique challenges; there had been no advances in treatment in 13 years. This medical device study involved performing a biopsy, growing the patient's cartilage for 21 days, and re-implanting it to replace defective cartilage.

But that was only the beginning of the complex issues we faced. Patients were generally healthy, so we had to develop an advertising campaign to spread word of the study. We have done it often, and successfully, with two goals: to

attract the proper patient population and to give the trial a polished, professional appearance that made it attractive to clinical sites. The investigators we needed were used to performing surgeries and sending patients back to their primary care physicians, so we had to win their enthusiasm for performing frequent and long-term follow-up visits – something they were not at all used to. In addition, the patients were young and fundamentally healthy – especially after a successful surgery. Yet for the study to be a success, we had to keep them involved for seven years of follow-up. Seven years!

## Solution: we stopped acting like a CRO, and did what the patients do

We jumped into social media in a big way. We friended them. We found texting to patients' smart phones to be an especially effective way to stay in touch. There were many things we had to do that aren't what a CRO normally does. But then, that's what we do best: adapt to whatever unexpected challenges the project presents.

# MEDICAL DEVICE

The Premier Research logo features the word "premier" in a lowercase, sans-serif font above the word "research" in a similar font. A white circular arc is positioned to the right of the text, partially overlapping the letter "h" in "research".

premier  
research



# We Do Whatever It Takes ... Not What Everyone Else Does

## Study Description:

Large, long-term, randomized orthopedic biologic knee study involving an autologous chondrocyte transplantation system.

## Therapeutic Area:

Orthopedics.

## Indication:

Damaged knee cartilage in patients who have had inadequate response to conservative treatment.

## Geographic Scope:

25 sites in the U.S.

## Patient Population:

233 patients.

## Enrollment Period:

Initial surgery followed by seven-year follow-up required by the FDA.

## Outcome:

Patient follow-up is still in progress, and will be for several years more. To date, we have been successful at keeping patients involved long after initial surgery resolved their problem.



IT'S WHAT WE DO. BEST.™