

CASE STUDY

AES Saves Up to 76 Months of Enrollment Time For this Pediatric Depression Program

AT A GLANCE

Indication: **Pediatric Depression**



Enrollment
time saved:

56 months
(protocol 1)

76 months (protocol 2)

THE CHALLENGE

With this Phase III, 2-protocol program, the sponsor hoped to extend the label of its antidepressant drug to children and adolescents. Once enrollment began, sites' enrollment rates were far below expectations for several reasons:

- Children rarely say, "I'm depressed."
- Parents may not recognize the symptoms, know how to communicate with their child about depression, or feel comfortable acknowledging their child's depression.
- Parents are particularly reluctant to enroll their children into antidepressant studies.
- The protocol required numerous weekly appointments.

Faced with these challenges, the clinical trial team realized that its timelines were unrealistic and that reaching randomization goals would be extremely difficult, if not impossible, without our reliable enrollment support.

THE PLAN

Accelerated Enrollment Solutions (AES) was hired to support 89 sites in the US and Mexico over 16 months.

To address the situation, AES surveyed several thousand households about childhood depression, then designed 2 sets of materials: one for parents of young children and one for parents of adolescents. Select materials were customized to country-specific needs, and great care was taken to meet the sponsor's health literacy standards.

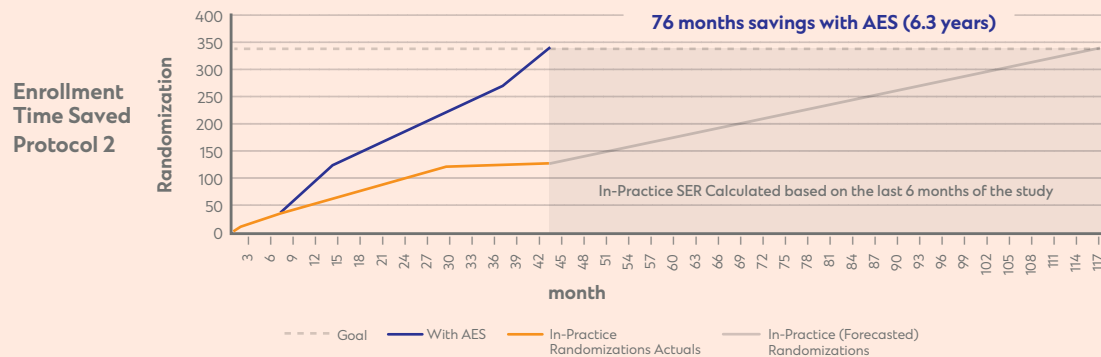
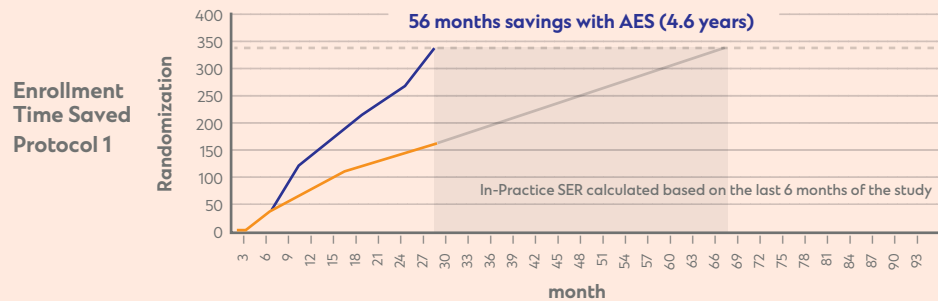
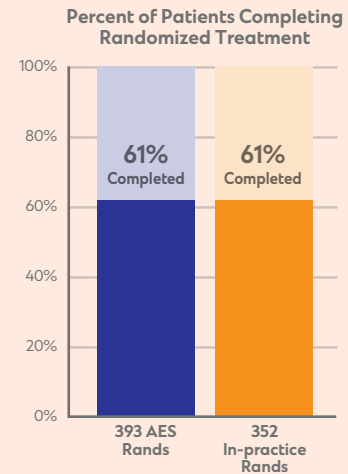
Campaign tactics included:

- Direct mail (US only) targeted to 7.7 million opted-in depression contacts (30% indicating children in household) from our proprietary database of 100+ million households
- eRecruitment (online health networks, keyword campaigns, display ads, social networking)
- Television, radio, print
- Education video for parents
- Website landing page

THE RESULTS

AES contributed 393 enrolled patients (53% and 59% of randomizations, respectively, for Protocols 1 and 2), and saved 56 months of enrollment time for Protocol 1, and 76 months for Protocol 2.

- Analysis also showed that the quality of our patients was similar to in-practice patients, with 61% of both groups completing randomized treatment.



About AES

Accelerated Enrollment Solutions (AES) is the new standard in clinical trial productivity. Our innovative and integrated site and patient services secure the success of clinical trials by providing enrollment, timing, and budget certainty.

16870819

Corporate Headquarters

2 Walnut Grove Drive
 Horsham, PA 19044
 1.215.323.9000 (press 2 to learn more)
globalAES.com

Email: enrollment.certainty@globalAES.com