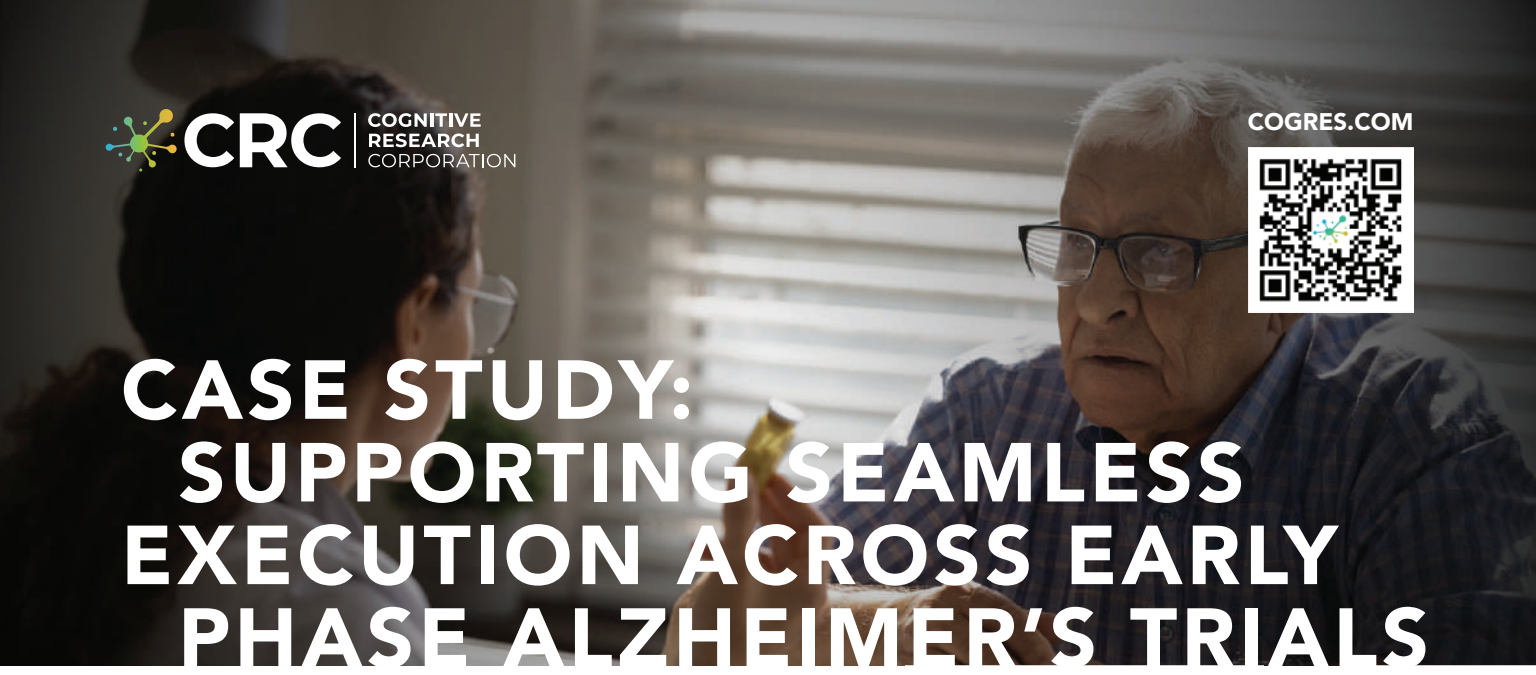

CRC COGNITIVE RESEARCH CORPORATION

COGRES.COM

CASE STUDY: SUPPORTING SEAMLESS EXECUTION ACROSS EARLY PHASE ALZHEIMER'S TRIALS

— background

CRC partnered with a sponsor developing a novel Alzheimer's treatment to support three consecutive early-phase studies during the COVID-19 pandemic. Our collaboration enabled the program to advance efficiently from first-in-human (FIH) through open-label extension (OLE) long-term safety evaluation.

- **Trial A:** Phase I FIH study in healthy volunteers (47 subjects, 1 site)
- **Trial B:** Phase Ib/IIa study in Alzheimer's patients (158 subjects, 18 sites)
- **Trial C:** Phase II OLE in rollover and de novo patients (121 subjects, 13 sites)

— CRC solutions

CHALLENGE	SOLUTION
Subject Participation Reservations Due to COVID-19 (Trial A)	Engaged a highly experienced FIH site and coordinated closely with site and sponsor leadership to address enrollment barriers.
Inefficiencies from Intermediary Consultant Oversight	Recognizing CRC's effective oversight, the sponsor opted to manage the trial directly through CRC. This improved communication, reduced costs, and enabled faster decisions.
High Turnover Among Vendor Support Staff	Increased oversight, maintained consistent communication, and coordinated closely with the sponsor to ensure continuity and on-time database lock.
Compressed Timelines for SAD & MAD Studies	Collaborated with sites to improve enrollment terms, implemented weekly recruitment calls, and maintained near-daily communication with the sponsor. Drafted the OLE (Trial C) protocol to support Trial B recruitment and retention.

— outcome

KEYS TO SUCCESS

- Direct engagement with sponsor's medical monitor
- Transparent milestone & enrollment tracking
- Frequent coordination on screening & enrollment metrics
- Trusted site relationships & proactive oversight

OUTCOME

The early-phase program was completed **ON TIME** and **ON BUDGET**, positioning the sponsor to advance to the next stage of development.

CRC's approach reduced overall costs and improved coordination, leading to successful database locks and timely milestone delivery.

The project's seamless execution led to additional collaborations.

LEARN MORE

FACING TIGHT CLINICAL TIMELINES?
CONTACT US AT info@cogres.com.