



HEALTH DATA TO PROTECT  
AND IMPROVE LIVES

# SOLVING STUDY CHALLENGES

## HOW EMSI POWERS THE SISTER STUDY

### CLIENT PROFILE

The National Institute of Environmental Health Sciences (NIEHS) was established by the National Institutes of Health in 1966 to research factors affecting environmental health. The NIEHS seeks to understand the interplay between environmental exposures, human biology, genetics, and common diseases to help prevent disease and improve human health. In 2003, the NIEHS awarded the University of North Carolina a grant to study the environmental, lifestyle and genetic factors that may make some women more likely to develop breast cancer. The resulting study, “Environmental and Genetic Risk Factors for Breast Cancer” grant# N01-ES-45525 (also called the “Sister” study), targets sisters of women with breast cancer. Sisters share some of the same genes and other characteristics but may be affected differently by environmental factors than their siblings.

### PROGRAM CHALLENGES

The first challenge was balancing lab capacity, geography and rescheduling to meet program timelines. Lab capacity was limited to accepting 25 specimens a day while reaching a recruitment goal of 52,000 women over five years. Women in the study could not have received a breast-cancer diagnosis themselves and must have a sister with breast cancer. After finding these unique participants, managing visits by geographic region while monitoring scheduling and rescheduling rates was essential to balancing program timelines with lab capacity. Initial home visits to collect data and specimens occurred between 2005-2010 with regional launches requiring rapidly scalable scheduling and collections.

### Challenges Met

- Balancing limited lab capacity, geography and rescheduling to meet program timelines
- Developing and deploying examiners trained to assist challenged participants
- Ensuring data accuracy during involved and extensive collections

The second challenge was choosing the right examiners for this unique participant pool. Some participants were diagnosed with breast cancer after the study began and were ill from undergoing treatment. Specially trained and experienced examiners were required to help participants complete the collection requirements.

Along with choosing the right examiners, EMSI's training and protocol design required ongoing optimization. Assisting participants and adapting to their needs was fundamental to accurate collections.

The third challenge was precise data gathering. Besides an extensive questionnaire, collections included biologic (blood, urine, toenails) and environmental (dust) specimens. Ill participants required extra help with collections during the visit, such as clipping toenails and collecting urine. These factors could not be anticipated during scheduling. Monitoring to ensure accuracy and proper execution of the study protocol was essential.

## **SOLUTIONS**

EMSI's internal management protocols and processes evolved over time to match the needs of the participant pool and study goals. We calibrated visit scheduling to match limited lab capacity of 25 specimens per day while meeting program timelines. From the first 52,000 visits to periodic follow-ups of 3,000-4,000 participants that are ongoing today, our scalable operations have met every visit milestone.

As some participants needed special care and assistance while recovering from chemotherapy, we made these blood draws easier and more efficient by adapting our training and scheduling protocols. During visits, EMSI examiners reported that some blood draws were too difficult to perform due to compromised veins and participant weakness. However, they also discovered many of these participants had ports installed for ongoing treatment. To ensure safe specimen draws, we arranged to meet these participants at their doctors' offices. Clinic staff collected samples for both the office visit and the study, minimizing disruption and discomfort for participants. To increase participant satisfaction and retention, EMSI arranges for the same examiner to complete the visit whenever possible.

Lab kits for the study were complex, requiring extensive and detailed examiner training. Examiners collected urine, toenails, dust and seven vials of blood. The blood was stored in components of whole blood, serum, plasma, blood clots and packed cells, with exacting requirements on storage, volume and temperature. Participants were also required to complete a lengthy survey to be returned with the kit. We worked with our client to develop training that met both the technical and sensitive aspects of the study. Examiners efficiently gathered the data and specimens while adhering to all study protocols, minimizing error rates.

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## **ABOUT EMSI**

EMSI supports life science companies with fast, accurate biospecimen collection services essential for expanding patient access to lifesaving medical therapies. EMSI examiners are credentialed and undergo rigorous, client-specific training. They are regularly audited by our independent Quality Assurance team for accuracy and completeness and receive one-on-one intervention and retraining as required. EMSI also offers efficient retrieval and abstraction of participants' medical records. These services support epidemiological studies, post-marketing and outcome-based research and patient recruitment for clinical trials.

With real-time data, comprehensive patient engagement and local teams across the country, EMSI can handle the most challenging study population.