



Transplant, Allergy and Autoimmune

The Transplant, Allergy and Autoimmune (TAA) Therapeutic Area consists of dedicated research professionals with a deep understanding of the medical and operational challenges inherent in trials conducted in this therapeutic area as well as a strong desire to improve human health. TAA Project Leaders have strong relationships with the Key Opinion Leaders (KOL) in the field whose insights help create a scientifically sound protocol and drive patient recruitment. All staff members work collaboratively, within and across functional groups, and are empowered problem solvers to assure high quality deliverables on time and within budget.

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Highlights Include:

- Through the Division of Allergy, Immunology, and
 Transplantation (DAIT) Emmes served as the Statistical and
 Clinical Coordinating Center (SACCC) for the Consortium for
 Food Allergy Research (CoFAR) for over 14 years. CoFar was
 established to conduct multi-center clinical trials, observational
 studies, mechanistic studies, and basic research to develop the
 best treatment approaches to food allergies which resulted
 in over 50 peer reviewed publications and abstracts including
 publications in high impact journals such as the New England
 Journal of Medicine and the Journal of Allergy and Clinical
 Immunology (JACI). Emmes support included:
 - Design and analytical support of all clinical trials and observational studies of immune mechanisms in food - allergic patients
 - Protocol development and coordination
 - Web-based centralized data management and information dissemination
 - Regulatory support
 - · Safety monitoring
- Emmes previously supported the Immune Tolerance Network (ITN) again resulting in several key publications.
- Extensive experience in clinical safety and pharmacovigilance support in food allergy trials including the creation of processes for the collection, review, and assessment of SAEs and the safety data reconciliation processes to ensure appropriate monitoring of the safety of all human subjects.
- Proven track record of successfully managing and collaborating with sub-contractors such as Biological Specimen Repositories, Investigational Drug Manufacturers and Data and Safety Monitor Boards.

Key Data

- Decades of experience in autoimmune disease providing full-service support in 9 clinical trials in food allergy.
- Data driven site identification with established relationships with food allergy experts and clinics nationwide.

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