

Annual Congress on

# Rare Diseases & Orphan Drugs

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## Rare disease studies facilitated by taking study visits to the patients

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Patient recruitment and retention are key factors in establishing the objectives and ultimate success of clinical trials. These can be particularly challenging in rare disease studies where patients reside distant to investigator sites and may suffer from debilitating diseases making travel difficult. Patient advocacy groups have been playing a more influential role in drug development and commercialization especially in rare diseases. Advocacy groups represent the voice of the patient contributing to better clinical trial design by helping to remove barriers that made participation difficult or impossible. But many challenges remain. A patient-centric service model has evolved over the past years allowing study visits to be conducted at the patient's home where it is more convenient and comfortable than at the investigator site. By conducting selected protocol visits at home, workplace or other alternate location, ambulant healthcare providers offer a way for patients to participate in trials regardless of study duration, frequency of visits, disease state, distance to site and family, school, work or community obligations. By making trials more convenience and comfortable for patients, more patients are willing and able to participate and remain in the study. This innovative service model is available on a global basis and has been shown to triple enrollment rates and reduce patient dropout rates to 3 percent. Services include study drug administration, blood draws, clinical assessments, patient training and education and study compliance checks in all age groups, a variety of therapeutic areas and in all phases of development. This ambulant care service model provides a win-win benefit for all stake holders by providing patient's a convenient and comfortable way to participate in studies, offering investigators the ability to recruit patients from broader geographic areas, reducing development times for sponsors developing new therapeutics and ultimately getting life enhancing products to consumers sooner.

### Biography

Gail Adinamis is the Founder and CEO of GlobalCare Clinical Trials LLC, USA and has over 35 years of comprehensive global clinical trials experience including over 12 years of global trials management at Abbott Laboratories and Astellas. She has founded the in-home business model for study visits in 1992 and established and headed clinical trials divisions for three national home infusion companies and was the Founder, President and CEO of the first independent ambulant care service company for clinical trials. She is a Member of the Women Presidents' Organization, National Association of Professional Women and DIA and has been an invited speaker at several industry conferences and recipient of numerous awards/recognitions including twice being among INC 5000's fastest growing private companies and Game Changer and CEO of the Year.

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