



YOUR PARTNER IN FIRST-IN- HUMAN AND EARLY FEASIBILITY STUDIES

Successful performance in first-in-human and early feasibility studies is a critical milestone for medical devices. By providing valuable data that cannot be obtained from preclinical testing, these studies can expedite product development and optimize opportunities for bringing devices to market. Conducting first-in- human and early feasibility studies requires specialized product development and clinical trial expertise that smaller companies often lack. BBA can help fill this gap. We have a track record of partnering effectively with clients to deliver product readiness, regulatory and clinical support throughout this challenging process.

BBA serves as a lean, nimble extension of your team. We focus not only on how to position the product to demonstrate its mechanism of action, but also on determining the optimal patient cohort and understanding procedural considerations unique to your product. Minimizing risk during the process is important to us. So we have devised the robust, risk-based Desario™ decision-making method, which allows you to consider various use scenarios and performance/safety risks for the product and track resulting design refinements. We believe our holistic, cross-functional approach optimally supports preparation for first clinical studies and streamlines the path to successful regulatory approval. Along the way, our integrated team can offer insights into product and study design to anticipate favorable reimbursement and market access. Thorough early usage data, meanwhile, paves the way for adoption into hospital settings.

BBA CAN ASSIST WITH FIRST-IN- HUMAN AND EARLY FEASIBILITY PROGRAMS BY:

- 01 Engaging early in product development (at the concept phase)
- 02 Supporting your design decisions with input on use scenarios
- 03 Refine device design or instructions to best align with user requirements.
- 04 Designing studies to assess product performance, safety and patient outcomes
- 05 Offering strategic guidance on study design

AS A BBA CLIENT, YOU CAN EXPECT:

- 01 Seamless engagement as integral members of your team
- 02 Triage of key risks and opportunities to align across functions
- 03 Granular options for concurrent execution of program design including product design, risk management, regulatory and clinical development
- 04 Proactive, transparent review and decision-making
- 05 An unwavering focus on early patient experience, product iteration and regulatory positioning



BBA'S FIRST-IN- HUMAN TEAM OFFERS EXPERTISE IN:

- Product Design Readiness
 - Regulatory strategy and execution
 - Study design, planning and conduct
- CONNECT WITH BBA AT: info@bbacro.com or follow us on [LinkedIn](#) or [Twitter](#) today.