

CDT	BG-12 Program Team	SMT
<p><u>Core Members:</u> Clinical Development Manager Lead Program Medical Director Program Statistician</p> <p><u>Ad Hoc Members:</u> Clinical Trial Managers SMT Leaders Data Management Planning and Operations Clinical Communications Drug Safety and Risk Management Commercial Regulatory Affairs Preclinical and Clinical Development Sciences Research and Program Executive/Core Team Leader functional areas Drug Logistics Corporate Drug Compliance Statistical Programming</p>	<p><u>Core Members:</u> Medical Director, Medical Research (for each active TA) CDT Leader, Medical Research CMC Team Leader Preclinical and Clinical Development Sciences Team Leader Regulatory Representative Intellectual Property, Legal Business Planning, Finance Research Scientist New Product, Commercial Global Brand Manager, Commercial</p> <p><u>Ad Hoc Members:</u> CMC Line Function Representatives Preclinical and Clinical Development Sciences Line Function Representatives Medical Affairs</p>	<p><u>Core Members:</u> Clinical Trial Manager Project Medical Director Project Statistician Business Project Manager Medical Writing Drug Safety and Risk Management Clinical Data Associate Clinical Research Associate Clinical Business Analyst Contracts Manager</p> <p><u>Ad Hoc Members:</u> Clinical Development Manager Regulatory Affairs Clinical Logistics/Product Logistics BioAssay/Clinical Immunology BioStatistical and Clinical Programming Preclinical/PK and Metabolism Representative Corporate Drug Compliance Other function areas as needed</p>