5.0 SYNOPSIS

Protocol title	**Registry for long-term follow-up of safety and efficacy parameters of GBG study participants**
GBG number	GBG 107
Protocol Version	Version 1.0
Study design	This is a prospective and retrospective, international, multicenter, non-interventional, observational study for collection of long-term safety and efficacy parameters of former GBG study participants.
Primary Objective	• To evaluate **long-term-survival endpoints**
Secondary Objectives	• To determine long-term **toxicity** associated with study therapy • To determine **anti-hormonal therapy in HR+ breast cancer** after study participation • To determine **further anti-cancer therapies** after study participation • To determine **pregnancies** after study participation and their outcome • To determine impact of study treatment on **Quality of Life (QoL)** after study participation. • To assess and compare **other study-specific long-term-outcome objectives** as defined in the respective study protocol.
Exploratory Translational Research Objectives	• To evaluate the association of **potential new biomarkers with resistance** to breast cancer treatment for early breast cancer based on relapse specimens
Inclusion criteria	• Participation and treatment in a GBG clinical trial for early breast cancer. • Prospective Registration: written informed consent according to local regulatory requirements prior to data and biomaterial collection.