Assessment of incidence and severity of adverse reactions to the ultrasound contrast agent sulfur hexafluoride (SonoVue®) in contrast-enhanced ultrasound

Aims:

1) To retrospectively assess the incidence and severityof adverse reactions to SonoVue® in CUES applications across multiple departments (Gastroenterology and Hepatology, Cardiology, Radiology, Pediatrics) at the Kantonsspital St. Gallen, its associated hospitals and other Swiss institutions over the last 10 years, based on complete documentation of SonoVue® use and associated adverse events.

2) To evaluate pharmacovigilance databases, including the World Health Organization's (WHO) global database of medicinal product side effects, the FDA Adverse Event Reporting System (FAERS), and (if accessible) Swissmedic, for allergic events related to sulfur hexafluoride (SonoVue®, Lumason®) since its approval in 2001.

3) To investigate patient characteristics and possible mechanisms underlying allergic reactions to SonoVue® through clinical and *in vitro* allergological assessments in affected patients and matched controls undergoing CEUS.