[redacted]

Amendment to Statistical Analysis Plan (SAP)

[redacted]

PROJECT TITLE:	Safety and effectiveness of Pradaxa oral pellet formulation for treatment of acute venous thromboembolic events (VTE) and/or for risk reduction of recurrence of VTE in pediatric patients aged 3 months to less than 12 years in a real world setting: a prospective non-interventional study conducted in the United States
PRINCIPAL INVESTIGATOR:	[redacted]
SPONSOR	Boehringer Ingelheim
INSTITUTION:	UCSD/Rady Children's Hospital and the Children's Hospital-Acquired Thrombosis (CHAT) Consortium
SAP DATE:	July 23, 2025
DATA SOURCE:	Children's Hospital-Acquired Thrombosis (CHAT) Consortium
PREPARED BY:	[redacted] and [redacted]

Amendment to Statistical Analysis Plan (SAP)

1. Rationale for Amendment

Due to significantly lower enrollment (5 participants instead of the projected 300), the original statistical methods—designed to estimate the cumulative incidence of clinically-relevant bleeding events—are no longer appropriate. This amendment outlines revised analytic strategies to ensure transparency, data usability, and scientific value despite limited sample size.

2. Revised Objectives

2.1. Primary Objective

To describe characteristics of patients enrolled into the study while receiving Pradaxa pellets.

2.2. Secondary objective

To describe the incidence of adverse events (AEs), including AEs for which treatment was discontinued and serious adverse events (SAEs) (safety outcome).

3. Revised Analysis Strategy

Component	Original Plan	Revised Plan
Primary Analysis	Cumulative incidence	Descriptive and summary listings by participant
Safety Analysis	Group-level adverse event comparison	Summary listings, narrative safety assessment per participant
Missing Data	Imputation methods	Complete-case analysis; descriptively reported on missingness