Missing Data Working Group

The Working Group on “Estimands and Analysis in the Presence of Missing Data and Other Treatment Confounders” started the discussion with a presentation by Craig Mallinckrodt on “Preparing for Updated ICH Guidelines on Missing Data: Choosing Estimands”. The trial planning framework laid out in the presentation will be recommended in a future Addendum to the ICH E9 “Statistical Principles for Clinical Trials”. This framework allows for considering the disease state, drug specific considerations and stage of development when selecting objectives and estimands (i.e. measures of the treatment effect) for clinical trials. Intercurrent events (events that

happen post randomization and confound treatment, such as treatment discontinuation or rescue medication) will be defined upfront and how to deal with them. The statistical analyses will be specified only after the selection of the objectives, estimands and design. The working group will meet throughout the year to produce a template format that will cover these concepts in detail for a specific disease state.