Table 2: Predictive Analytics

Session 1-

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Session 2-

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**Scope:**

The roundtable discussion team defines Predictive Analytics as techniques used to make predictions about clinical safety and efficacy using data from analytical methods that measure physical parameters of a molecule of interest. Efforts to measure predictive physical properties of a molecule result in large and extremely valuable data sets. When these data sets are correctly structured, artificial intelligence (AI) or machine learning (ML) can be applied to better understand and predict the clinical impact of manufacturing processes, manufacturing changes, and process variability on product quality and clinical safety and efficacy. The goal of this round table is to exchange ideas on current best practices in predictive analytics and how these data sets can be converted most efficiently into product and process knowledge. We will also discuss how AI/ML can be applied to optimize the knowledge generated, to identify novel correlations between analytical data and clinical outcomes, and to design novel analytical approaches to improve Predictive Analytics.

**Questions for Discussion:**

1. Do we have gaps in the current predictive analytical methods and are there strategies or novel technologies to close these gaps?
2. Are there emerging technologies that are allowing better prediction?
3. Are the current strategies for collecting and storing these large data sets sufficient to effectively apply AI/ML? Do we have solutions for this if not? Do participants have data lakes or other strategies for data structure?
4. How can AI/ML be best applied to advance the field of Predictive Technologies? Does anyone have examples of how they are applying AI/ML in the predictive analytical space?
5. Do the data bases that are used in analytical development AI/ML contain clinical data currently, or are these data sets initially applied to better understand process?