Table 31: Acceleration and CMC - Novel Approaches to Enabling Acceleration

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Scope:

Over the past several years regulatory authorities have given companies different paths to reduce the time products spend in the clinic to help bring novel products to patience as quickly as possible. At the same time, the authorities clearly state that no additional CMC risks will be accepted for accelerated projects. This view brings CMC topics directly onto the critical path. The industry must find ways to bring safe and effective processes and products to the market with a much shorter timeline but with the same knowledge base and CMC risk portfolio. The on-going pandemic has put additional pressure on CMC timelines. There are many examples where industry has successfully answered the challenges. In this roundtable, we want to discuss different strategies that companies are implementing to insure a successful accelerated approval. How are you cutting corners to ensure the CMC data required for a successful submission is available? We should discuss specific examples and best practice so that we in the industry and the patient can benefit from these accelerated paths.

Questions for Discussion:

1. Are there specific strategies that have been put into place to accelerate a project to clinical or to BLA? Are the work plans for these accelerated projects fundamentally different?
2. Are there accelerated processes your company has put into place to meet a covid specific medical need that have been implemented, how much of this accelerated strategy can be applied to a standard accelerated project and how much will be implementable to standard projects to reduce efforts?
3. Is your company using knowledge management to support decision making and focus efforts in accelerated programs?
4. Are there specific software tools or other specific examples of how your company supports accelerated approval processes?

Discussion Notes:

How do we justify using historical data or putting off experiments?

- generic control strategy – identify parameters that are important in DS
- how is prior knowledge structured – part of risk assessment, iRisk captures prior knowledge (not the raw data) and speeds up the risk assessment process

How can you structure the data better for knowledge management?

- need lots of investments in automation

- how to link in quality and performance data with the risk assessment data?

Do companies have a standard accelerated timeline?

- What are people comfortable deferring? Is it a decision with regulatory involved? (should be yes, but doesn't always happen)
- Also need to consider molecule and indication to see what strategies are appropriate

How are models being used for acceleration?

- Would want to see more regulatory interaction throughout the year to get more of their perspective to convince internal
- One company doesn't include models in filing, only for process development to derisk or simplify experiments
- One company has talked with regulators on how to validate a model- tier based validation strategy based on risk of model implementation
- Need to consider what advantages can you get (reduction in analytics? more design space?) and can combine models with traditional experiment approaches
- Models can be used to defer experiments