MSP AG Agenda Topic Submission

MSP Meeting 4th July 2024

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Proposed Topics

Topic	Detail	Solution
Regulatory Consultation Process	Lack of speed and agility in scheduling Agency consultation aligned with speed of FDA. We respect the scientific judgement of Regulatory Agencies to arrive at different conclusions regarding vaccine licensing criteria based on similar data, however differences can affect the pace of access to vaccines that impact public health globally.	Developing a more agile consultation process would allow EMA and FDA scientific consultation to take place in parallel or even joint scientific advice could be helpful in allowing discussion to increase convergence. It would have a significant impact in reducing the trend of starting USA first and following with EU in a global study thus providing greater access to EU patients/citizens. It would also limit amendments as we would be more likely to launch with a globally acceptable protocol in the first step.

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EU CTR Review Process and Amendments Limiting EU Clinical Trial Contribution Compared to ROW	The inability to submit parallel amendments, and the need for protocol amendment submissions during RFI Part 1, and the impact of additional reviews required before starting studies. EU CTR timelines still present challenges in vaccines in influenza seasonality, for example, delaying Ph3 start prior Flu season.	Resolve ability to submit parallel amendments and lift restriction to start study on conditional approval. With respect to seasonal impact, in our experience, the Regulators are supportive and have suggested some mechanism to facilitate this process. It would be beneficial to acknowledge this and develop practical application of solutions going forward.

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Regulatory and Documentation Variability	Local demands are still made for part II documents and there is no scope for a sponsor to refuse or escalate to drive alignment as per regulation.	Develop process to truly harmonise part II documents – highlight non-compliance that is adding to sponsor workload and limiting fast start as per the spirit of EU CTR.
RMS Empowerment and Increased consultations	No triage of RFI is leading to inconsistent challenges for the Sponsor. Inconsistent timelines for approval processes i.e. early approval of Part II in anticipation of Part I is not advantages	Empowerment of RMS to group and triage RFI should be considered to prevent contradictory RFI, support education of EC and limit expansion of scope of EC in the review process
Standardise EC Process and Contribution	There is a lack of transparency in the EC's involvement in the review of PART I with some countries conducting joint reviews leading to duplicate questions or difficulty to address conflicting questions,	Linked to solution above – empower RMS to group and triage RFI Launch an EC education campaign and training

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Thank You

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