Table 9: COVID Therapeutics – How Are Analytical (HOS) Methods Being Used to Support Dramatically Shortened Development Timelines?

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Scope:

The COVID-19 pandemic has demonstrated that vaccine and therapeutic development timelines can be dramatically shortened. As of February, 2021 the FDA's Coronavirus Treatment Acceleration Program (CTAP) dashboard indicated that there were already over 590 drugs development program in planning stages, 430 clinical trials reviewed by the FDA, 9 treatments authorized for emergency use and one treatment approved. Covid-19 therapies under development cover a broad array of single agent treatments, including antivirals, cell and & gene therapies, immunomodulators and antibodies, as well as a number of combination therapies. In this round table, we will discuss how analytical methods (with a focus on HOS methods) are being adapted, innovated and applied to support the incredibly rapid pace of development across the wide range of different COVID19 therapeutic and vaccine modalities being studied.

Questions for Discussion:

1. What lessons have been learned in adoption, innovation and application of analytical methods in the accelerated development and QC of the different COVID19 therapeutic and vaccine modalities?
2. Has the pandemic driven adoption of new platform analytics and what challenges remain in terms of establishing robust platform analytics, particularly for newer modalities (e.g., cell and gene therapies)?
3. Has the pandemic accelerated adoption of new and emerging analytical and biophysical methods, particularly for newer modalities (e.g., cell and gene therapies)?
4. Will knowledge gained in the last year be transferrable and what, if any, will be the more lasting and general impacts on post-pandemic therapeutic development?
5. How has the pandemic changed the landscape for how academic, industry, government and regulatory communities can work together? What is working and where do opportunities still remain?