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Interacting with the Regulator during this COVID-19 time

I am excited at the level of research and development occurring around the world aimed at therapeutic interventions for COVID-19. It is easy to forget that Regulators are working through altered work environments which come with the social distancing and other policy measures impacting us all, both professionally and personally.

Still, there are deliverables to meet and outcomes to reach. So in interacting with the Regulator at this time, I keep the following in mind....

1. How might the Regulator be impacted by COVID-19?
Prioritising COVID19-related matters
Adapting to social-distancing measures
2. How might the part of the Regulator I am liaising with be impacted by COVID-19?
Resources diverted to address COVID-19-related matters
Communication delays
3. What do I need to factor into my planning at this time, to provide the organisation I represent with more realistic expectations?
Check formal Regulator communications
Patterns or trends from experience thus far

Three questions to ask yourself in this COVID 19 environment

- Have I reviewed relevant Regulator correspondence?
- What could I factor into my planning?
- What is unlikely to be impacted much (if, at all) during this time

How has COVID-19 impacted you?

Do you have a complex Regulatory activity which could value from an experienced Regulatory review? In addition to traditional Regulatory consulting services, EnimeraRegsPlus can support you through Regulatory Strategies and TGA Appeals. Contact Mary on enquiries@enimeraregsplus.com.au for a complimentary and in confidence discussion.

