Due to extreme forces of nature, all communication systems in your area are down (i.e. no phone, internet, cell phone, etc.). Therefore, you cannot contact anyone. What do you do to get your submission to your regulatory entities?

Country regulation changes have been announced and shared at the annual meeting. However, the Regulatory Coordinator didn't attend, and your site is left unaware of the changes. What do you do to ensure your site doesn't miss critical information?

Your contact at the regulatory entity is no longer there and you have an urgent request from your sponsor to confirm a specific trial requirement. How can you get the answer?

The regulatory coordinator has gone on sudden medical leave and there isn't a back-up. You are a new site staff member and discover that the coordinator forgot to complete a continuing review submission. What is your approach to alert the study investigator and team?

Your regulatory coordinator does not report for work and there is a critical submission deadline. You learn that she has taken a new job and will not be returning to work. How do you handle this situation?

Your country ethics committee has updated its processes from hard copy to electronic submissions. Your internet connection (line speed) is very slow and you are struggling to upload/send the large number of documents required for the submission. What is your plan of action?

The regulatory coordinator has relocated to another continent. You believe that a new protocol has been submitted for ethics review, but you are not certain of the timelines. In addition, you do not know when the submission deadlines are for the country approval. How do you handle your regulatory submissions?

There has been an update to a DAIDS policy. The site contact has not shared this information with the study team. It is discovered during a monitoring visit. How will you address this situation?

Your regulatory agency approval does not reference the newest requirement which you have to include in your submission. DAIDS wants this referenced in the letter but the regulatory entity is not responding to your requests. What do you do?

You are moving to a new location (e.g. to a new floor in the building) so that you have more space. This coincides with a submission deadline to DAIDS and your local country entities. What is your plan to ensure you meet these deadlines?

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