

Q-BITES

THE QUARTERLY NEWSLETTER BY



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The IP is Coming!!!

Space constraint is a huge challenge at site. Each study is supplied with numerous items such as files, courier boxes, questionnaire device, lab kits and many others. Though there might not be many criteria in storing these items besides being safely locked and having limited access, there is one item which has a set of criteria that needs to be adhered to when storing it: the Investigational Product (IP).

An IP would need a storage of specific temperature such as room temperature, fridge (2°C – 8°C), freezer (-30°C), etc. The storage would also need continuous electrical supply to ensure the required temperature is maintained throughout. Daily temperature monitoring would also need to be done. Even though all the facilities above might be available at site, the bigger challenge is having the space to store the IP in the said IP room, fridge, or freezer.

So how do you ensure that there is sufficient space before the IP arrives and not go hunting for the exact storage space once the IP has arrived? Here are some pointers:

1. The first step is to always determine the temperature requirement for the IP. Once temperature requirements are known, the storage place can be decided – IP room, fridge, freezer, etc.
2. Evaluate the current storage space available in the place identified to store the IP.
3. To compare the storage space adequacy with the IP being received, obtain the following information:
 - Type of IP packaging – tablet in bottle, tablet in boxes of blisters, vials in boxes, etc.
 - The dimension of the IP packaging being received – length, height, width of the IP box, size of the IP bottle, etc.
 - Quantity of initial shipment – how many boxes/bottles of IP will site receive initially?
 - Quantity/Frequency of subsequent shipment
 - is the quantity/frequency fixed?
 - triggered upon randomization?
 - triggered upon dispensation?
 - ordered by site/CRA? etc.
 - Be aware of target number of patients and expected recruitment rate - through previous studies, PI's recruitment plan, etc.
4. Use the information above to estimate whether storage space will be adequate.

If not adequate, don't panic. Look for alternate storage space. Or discuss with CRA to have a shipment schedule that can accommodate the storage space at site.

Jason and the Shops

Jason worked in a flower shop. Every day he would open the shop and arrange the fresh flowers. He will keep track of all the sales. During lunch time he will eat the home cooked food he brought from home. As soon as finishing his lunch, Jason would spray water on all the remaining flowers to keep the remaining flowers fresh throughout the evening. This was his routine every day. He does this same work each day as if he was pre-programmed to do so.

Unfortunately, after working for three years, the flower shop went out of business. Jason did not know what to do. He was unemployed. He decided to ask help from his uncle who owned a shop that sells firecrackers. Jason's uncle decided to help him and hired him to work in his shop.

After three months, Jason's uncle noticed that the sales of his firecrackers was dropping. He did not know what was happening. When Jason's uncle asked him, Jason said he did his work correctly.

So, one day, his uncle decided to come and watch Jason at work. Jason opened the shop and arranged the firecrackers. He kept track of all the sales. During lunch time, he ate the home cooked food he brought from home. As soon as finishing his lunch, Jason started spraying water on all the remaining firecrackers as how he used to do it in the flower shop. He has been doing this every day. His uncle was shocked. No one would want to buy wet firecrackers.

Jason never understood the purpose of his work. He kept on doing his work without questioning and taking the effort to learn about his job. The tasks that he performed worked in the flower shop but not in the firecracker shop.

It is always important to know the purpose of the task that we execute daily in our work and not do it just for the sake of doing it. Without knowing the purpose, we might be misguided to do the wrong thing.

Let's learn the purpose of each task that we perform and ensure together that we don't end up with wet firecrackers.

