DAIDS Applied Research Training (DART) Regulatory Updates

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Regulatory Updates Activity

What is it?

The objective of the following activity is meant to facilitate table group discussion on Regulatory Updates for participants to be able to understand, navigate, and handle the multiple challenges present in the clinical trials regulatory landscape.

During this activity participants will work in three (3) team-based exercises. First (1st), they will brainstorm general ideas and strategies needed to stay current on regulatory changes across the world. Second (2nd), participants will be presented with several roadblocks to determine the impact that these could potentially have on their device strategies. And third (3rd), participants will be prompted to write and reflect on how they would will implement these new strategies at their sites.

In the subsequent sections you will find the instructions and materials needed in order to complete this activity.

When can I use this activity?

This activity is good for a variety of events and purposes. The following list shows alternatives ways to use it:

- Self/Group -Reflection and reviewing concepts learned during an event
- Relationship Building
- Cooperative Learning
- Team Building
- Critical Thinking
- Refresher Training
- Risk Analysis
- Change Control
- Training Meetings/Events
- Conferences
- Group Annual Retreat
- Office/Departmental Meetings

What Materials / Resources do I need?

- Regulatory Updates Facilitator Instructions 15Jan2020
- Regulatory Updates Slide Deck 15Jan2020
- Regulatory Updates Worksheet 15Jan2020
- Regulatory Updates Roadblocks 15Jan2020
- Regulatory Updates Worksheet Handout 15Jan2020
- Regulatory Updates Poster 15Jan2020

- Large Super Sticky Notes – Twenty (20) sheets per table
- Markers

How long does it take?

Allow approximately Forty-five (45) minutes for the entire activity.

How do I prepare?

First, access the DART website and verify you have access to the course, then proceed with the following steps:

- Open the file: Regulatory Updates Slide Deck 15Jan2020. Review the Power Point presentation and determine if you will want to use this during your activity. Feel free to add information or customize for the needs of your site.
- Open the file: Regulatory Updates Worksheet 15Jan2020 and print on standard paper and distribute individually to each participant.
- Open the file: Regulatory Updates Roadblocks 15Jan2020 and print on standard paper, double-sided on regular paper or cardstock. Cut to size and distribute one card at a time during (2) to three (3) times in intervals of ten minutes throughout the activity.
- Open the file: Regulatory Updates Worksheet Handout 15Jan2020 and print on standard paper and distribute individually at the end of the activity.
- Open the file: Regulatory Updates Poster 15Jan2020 and print on an 18" x 24" or 24" x 39" paper size (optional) or use a blank sheet of paper or a whiteboard and distribute one per table.

How do I do it?

Now you are ready for the next steps. As a facilitator do the following:

- Distribute the Regulatory Updates Worksheet individually during the activity.
- Instruct participants to use the Regulatory Update Worksheet provided as a guide and to work with their table group to generate strategies, to be implemented by site staff, in order to combat the challenges of navigating the changing regulatory landscape.
- Convey to participants to brainstorm ideas/strategies that site staff need to consider to successfully stay current with regulation changes.
- The speaker will report answers to the other groups when called upon by the facilitator. Ideas should be general and not specific to country or local ethics.
- At about ten (10) minutes into the activity, walk around to the tables and provide one (1) Roadblock card to each table (repeat this step two (2) to three (3) times in intervals of five minutes). Ask participants to think about and discuss how this Roadblock will impact their strategies and if there are any other Roadblocks that might have an impact. Strategies may be updated as applicable.

- Have participants share their ideas with their table group and remind them of the activity time frame.
- Remind group of their time frame for completing their activity. (Suggested time period to complete activity per group twenty (20) minutes. Adjust a needed).
- Once participants have come to a consensus with four- five (4-5) ideas, ask them to post their results on the Poster Board using the Super Sticky Notes.
- Distribute the Regulatory Updates Worksheet Handout at the end of the activity.

How can I modify this activity?

Don't want to use the provided content/samples in this activity? That will be perfectly fine! The benefit of this activity is that you have multiple ways to go about it. For example, you can substitute the road blocks provided with some that you or your staff might have experienced at the sites or look within the FDA, EMEA sites for Regulatory updates and adapt as needed.

Another alternative is to have your staff differentiate the type of strategies they have identified, sort them by themes/characteristics and draw a list of actions they will take if presented with unexpected regulatory changes and how they will minimize the impact of these.

Another alternative, is to print all the Regulatory Updates Road Blocks on regular paper, cut out individually and place them in a basket in the center of the room. You can proceed to direct participants to draw one road block at a time for them to read as a group, identify the nature of the challenge, who will be responsible party to implement/apply this and then report back to the larger audience.

Also, you can print the following Regulatory Updates Road Blocks on a regular piece of paper, insert them in folders and distribute them by table groups.

1. 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 within the required timelines?
2. 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?
3. 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?
4. 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 the submission. What is your approach to alert the study investigator and team?

5. Your regulatory coordinator does not report for work and there is a critical submission deadline. You learn that they have taken a new job and will not be returning to work. How do you handle this situation?
6. Your country ethics committee has updated their 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?
7. The regulatory coordinator has relocated to another continent. You believe that the 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?
8. 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?
9. 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?
10. 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?