

EFS Site Best Practices Workshop

Chip Hance

March 6th, 2019



Welcome to First Ever EFS Best Practices Workshop

Meeting Objectives:

- To create a forum for exchange between sites and partners for improvement of the ecosystem
- To identify common challenges that could be tackled with follow-up collaborative efforts
- To be one more step on the road to FDA's stated vision:

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world.

Our Requests of You

Session Leaders:

- Engage the audience; seek broad participation; keep the discussion moving; translate into possible actions and recommendations

Participants:

- Be active; establish new networks; benchmark others; share results when you return home; join future efforts

LEGAL REMINDER

Meetings of this kind are an example of lawful activity under federal antitrust law because the focus of the meeting is on government action or policy, including the industry's responses or positions taken with respect thereto. However, antitrust monitoring is needed for companies' own protection since they are direct competitors meeting together. These meetings need to stay within protected subject matters and be monitored to avoid inappropriate areas, such as:

- Pricing, price terms, marketing plans, or new products
- Company's individual decisions regarding selection of suppliers or customers
- Other proprietary or competitively sensitive information

Today's meeting will follow the written agenda and there will be no discussion of pricing or other prohibited topics. If the discussion veers into those topics, we will terminate the discussion. If you have questions or concerns about the propriety of a discussion, please raise it immediately, and we will determine how best to proceed.

THANK YOU FOR BEING HERE

- Slides to Liliana or Dan
- Coffee, tea, pastries, and fruit in the next room (Thank you, Brandon)
- Bathroom codes

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