

OMB Control No. 0910-0360
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Sponsor and Payor Feedback for the Early Payor Feedback Program

Intro Script for Payor Feedback Calls:

Hi, How are you?

Thanks again for being part of our Early Payor Feedback Program. Today I'd like to give you a quick update on our program, go over a few questions we have about your experiences in the program, go over some feedback received from the sponsors, and answer any questions you may have.

Overview of the current program –Since 2016 we've matched XX companies with the XX participating payors –XX interactions, majority are 1:1 with the company and payor, XX have had payors join their FDA pre-submission meeting.

Email to set-up Payor Feedback Calls:

Hi Dr. XXX,

How are you doing?

CDRH's Payor Communication Task Force (PCTF) would like to thank you for partnering with us to provide feedback on clinical trial designs and data collection plans, especially for innovative medical devices. As we approach the XX-year anniversary of this program, we wanted to touch base again and hear from you about what is working well and if there are any items you would like to change or improve. Also, we conducted a survey of companies who have participated in the program and look forward to sharing their comments when we connect.

Let us know when a good time between now and the end of XXX to discuss your thoughts and provide the feedback mentioned above.

Hope all is well!

Kind Regards,

XXX

Intro Script for Sponsor Feedback Calls:

Hi, How are you?

We hope that your participation in the Early Payor Feedback Program has been a positive experience. And we would appreciate your thoughts about your participation, so that we can continue to make this program as impactful as possible. I'd like to run through the questions that we sent you via email. Shall we start with the first question from the email?

- How did you find out about the Early Payor Feedback program?
- Why did you choose to use this program?
- Did you find value in your payor interaction? If so, what was the value of the feedback received? Did you find any of the payors' feedback more helpful than others?
- How did your participation in the payor program impact your clinical trial development or FDA submission?
- Do you have any general feedback to improve the program?
- Would you be open to publicly comment/share your experiences with the opportunity?

Email to set-up Sponsor Feedback Calls:

Greetings,

We are reaching out to you because in the past, you have participated in the CDRH Early Payor Feedback Program.

We are excited to share with you that we are currently working to make our programs even more impactful. Below, you will find several questions that we would appreciate your input on. You may provide your response via email, or if you prefer, we can have a discussion over the phone.

We look forward to getting your thoughts within the next month, and we appreciate a response as soon as you can.

- In general, what would you say is working well about the Early Payor Feedback Program?
- Is there anything you would want to change or improve?
- We hope to do more outreach and promotion of our Early Payor Feedback Program. Would you be willing to go on record supporting the effort?
- As this is truly a "team" effort, we'd like to be sure you know we are a resource for you all as well. Are there any questions about CDRH/programs you have? Connections we can help you with?

Thank you and we look forward to hearing your thoughts!

Best,

CDRH Payor Communication Task Force