

**FDA Webinar- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices Final Guidance**  
**Moderator: Irene Aihie**  
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**1:00 pm ET**

Operator: Welcome and thank you for standing by. All participants will be in listen-only mode until the question-and-answer session. At that time you may ask a question by pressing Star followed by the number 1 to ask a question.

Today's conference is being recorded. If you have any objections you may disconnect at this time. I'd now like to turn the conference over to Irene Aihie. You may begin.

Irene Aihie: Hello and welcome to today's FDA webinar. I am Irene Aihie, of CDRH's Office of Communication and Education. On September 6, 2017 the FDA issued the final guidance document, Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices. The guidance outlines the Agency's recommendations for developing safe and effective devices that exchange and use patient information electronically.

Today, Heather Agler, Senior Science Health Advisor in the office of the Center Director here in CDRH, will present an overview of the final guidance. Following the presentation, we will open the line for your questions related to information provided during the presentation. Additionally, there are other

Center subject matter experts here with us today to assist with the Q&A portion of our webinar.

Now, I give you Heather...

(Heather): Thank you. So during this Webinar we are going to do an overview of the guidance which will include key definitions, an introduction, background and scope, the design considerations for interoperable medical devices and also the pre-market commission content. And then that will be followed by a question and answer session.

So just so we're on the same page I'd like to go over the key definitions that are found within the guidance document and the way that we have defined certain terms. Interoperable medical devices we have defined them as those that have the ability to change and use information through an electronic interface with another medical or non-medical product, system or device.

Interoperable medical devices can be involved in simple, unique directional transmission of data to another device or product. Or in more complex interactions such as exerting command and control over one or more medical devices. Interoperable medical devices can also be part of a complex system containing multiple medical devices.

The other key term that we use within the guidance document is electronic interface. And we define this as the medium by which systems interact and/or communicate with each other thereby allowing the exchange of information between systems. It (brings) both a type of connection and when we say type of connection we mean like whether it's a USB port or wireless connection, whatever that may be.

And then also the information content. And it is the medium by which a medical device exchanges and uses information with other equipment or other medical devices.

So the purpose of the guidance is to promote the availability of safe and effective interoperable medical devices and to provide considerations to you in the development and design of these interoperable medical devices. Also to clarify the contents that you would submit in a pre-market submission to support an interoperable medical device.

And then finally to provide recommendations for what can be found in the labeling. FDA has been involved in medical device interoperability for many years. Here is just a recap of some of the highlights. In 2004 we hosted the second meeting of the medical device plug-and-play interoperability project. Also in 2010 there was a medical device interoperability workshop. In 2012 we co-hosted a summit on medical device interoperability with (Amy).

And then in 2013 we had a special recognition of the set of standards that supported both medical device interoperability and also cyber security. Then in 2015 we also had a workshop on promoting semantic interoperability of laboratory data. And then of course what we're here talking about today we published the draft guidance document in 2016 and now have published the final guidance.

So next to talk about the benefits of interoperable medical devices: really with the increase in new technologies that we see, there is this sort of desire to connect medical devices with one another and to share that data that is available. And with the advent of wide adoption of electronic health records it's also sort of driven that desire to use medical device data for different applications.

Interoperable medical devices have the potential to foster new, innovative health care solutions at a lower cost. And also to foster information sharing between devices and systems and across manufacturers.

The use - information from medical devices can be used in many ways including displaying and storing, simply displaying and storing the information, interpreting or analyzing the information or automatically acting on or controlling another product, such as a close-loop system may be looking at the different vital signs from a patient and may use some sort of automatic control to adjust patient treatment.

And systems that include interoperable medical devices may be composed of existing devices, products or technologies acting together to achieve a function different from the individual medical devices. In our guidance document we have a section on considerations for medical device manufacturers.

So these are things to consider when designing devices. We suggest designing systems with interoperability as an objective. So think about this upfront when you're thinking about your device; conducting appropriate verification, validation and risk management activity. And specifying the relevant functional performance and interface characteristics in a user available manner such as labeling.

So the scope of the guidance the guidance itself provides manufacturers with the design considerations when developing interoperable medical devices. Recommendations regarding information should include in a pre-market submission and recommendations for what to include in device labeling.

This document focuses on the information content exchange over the connection. And it does not focus on aspects of the physical compatibility. So although we are concerned about the physical connection, we do feel it's important to specify whether it is a USB port, a wireless connection; we are more focused on what is actually the information content exchange, the format, the context, the type of information that is being actually exchanged over that connection.

This document is not intended to provide guidance on whether or not a specific product or modification to a product requires a pre-market submission. And we intend for this document to compliment other FDA guidances. The pre-market discussion within the guidance applies to the follow pre-market submissions; 510(k)s, de novo requests, PMAs, product development protocols, humanitarian device exceptions and biologic license applications.

So the following considerations should be appropriately tailored to the selected interface technology and the intended use environment for the medical device. So when you have an interface on your device you should be thinking about what is the purpose of that electronic interface. What could it be used for, you know, is it just meant for the manufacturer to have access for updates or is it meant to connect to other systems, other medical devices.

Who are the anticipated users of the medical device? These could be – it could be used by home healthcare workers or integrators within a hospital or clinicians. So think about who might be your users of the device or the interface on the device.

Also think about risk management. When you have an interface on the device what types of risk does that introduce to the device itself? And how might

those risks be mitigated? And verification and validation, you know, in what ways would you need to verify and validate the interface on the device. What labeling considerations should you have?

So what would you want to put in the labeling so that people could use the interface properly in the way in which it was intended. And then also the use of consensus standards. You know, obviously if we are connecting medical devices and we want them to be able to exchange information, use that – there are some standardization involved with that data.

You're one step closer to being able to use that data in the proper way. And having sort of the same, you know, and defining the different exchange parameters in the same way. So we highly suggest the use of consensus standards where it is applicable.

So getting into the purpose of electronic interface so device manufacturers should consider the purpose for each of the electronic interfaces found on the device. Manufacturers should consider the level of interoperability needed to achieve the purpose of the interface. You know, is it purely just semantic interoperability? Is there context? Is there other things that need to be known in order to be able to use the data in the way in which it is intended.

As well as what information is necessary to describe the interface. Design considerations may be different for different types of electronic interfaces. So elements that should be considered include but are not limited to the following. The types of devices it is meant to connect to. So, you know, are you meant to connect to very specific devices, are you meant to connect to a broad range of devices or are you merely providing an interface so that anybody can download information off that particular device.

So what are those types of connections; the type of data exchange taking place, what standards may be used, the need for time synchronization? If there are going to be several devices connected within a network and you need to know sort of what artifacts are happening at what time you would want those particular devices possibly to have time synchronization so that you can follow the sequence of events.

The method of data transmission and necessary timeliness and reliability of information; that this is information that you're going to use to make real time patient decisions; the method of data transmission. Any limitations or contra indications associated with use of the electronic interface. The clinical context, anticipated use of the interface and the functional and performance requirements of the device.

In addition to how the interface would be used you also should think about who are the anticipated users. So you should – manufacturers should determine the anticipated uses for each of the electronic interfaces and determining the anticipated users will help in appropriately applying risk management strategies for activities such as developing appropriate instructions for use and setting limitations for the use of the device; including contra indication, warnings and precautions.

It should consider the different users when designing the device and developing the instructions. So instructions may vary a lot depending on who it is that may be using the device. So users, operators and clinicians need to know the clinical uses and potential risks relevant to the use environment and the clinical task at hand.

Equipment maintenance personnel and hospital/clinical engineers need to know what actions to take to verify correct configuration and operation. They

need to ensure that the system is performing as specified. IT professionals need to understand the performance needs and security requirements of the devices connected to the networks they maintain and operate. Systems integrators may need to know the capabilities of the component so that they can perform adequate risk management and validation.

And finally patients may need to know specific instructions on how to use their device in a home environment. In addition to the expected users manufacturers should also consider any malicious users or attackers in the design of the device. These considerations may influence whether the manufacturer places certain limitations on the users of the device or limitations on how the device may be used.

Developing different instructions for different users may help mitigate the risks.

And so also risk management – you should consider both intended and unintended access through (the) interface. In balance how to allow intended access by implementing security features to restrict unintended access to the medical devices and consider reasonably foreseeable uses and misuses of the electronic interface.

And develop an ongoing process for identifying hazards, estimating and evaluating associated risks, controlling these risks and monitoring the effectiveness of the controls over the life cycle of the device.

So these considerations really as I said should be thinking about the entire life cycle. And when you see additional risks post-market they really should be feeding back into the design of the device and see if there are any mitigations need to be made.



So we mentioned security. I would like to say that we don't get into depth about cyber security within this guidance document. We have guidance documents available on cyber security both pre-market and post-market. We do have a Webpage that is pictured here where you can go to and get information and other resources on cyber security.

But we wanted to, you know, mention that we understand that it is a balance that while we want to share data and have interoperable medical devices, that we also understand the need to have appropriate security to balance that as well.

So we also focus on the potential hazards, safety concerns and security issues introduced when including an electronic interface. For example in part of the evaluation in design process, manufacturers should consider the following; whether implementation and use of the interface degrades the basic safety or risk controls of the device; whether implementation and use of the interface degrades the essential performance of the device and whether appropriate security features are included in the design.

And finally whether the device has the ability to handle data that is corrupted or outside the appropriate parameters. So while we want our devices to be able to talk to one another when you're talking about medical devices that being part of a network or talking with other medical devices and we want the information to be understandable, we also really need to consider the safety features with medical devices. Because the last thing we want is for an issue to come up that could adversely affect patients.

An interoperable system should maintain basic safety and essential performance during normal and (fault) conditions. A manufacturer should

design an interoperable medical device that can appropriately mitigate risks associated with possible error scenarios such as failures and malfunctions caused by direct or indirect connection of - in intended devices; failure or malfunctions caused by invalid command; failure or malfunctions caused by receiving and processing erroneous data or command. And failures or malfunctions caused by not adhering to the nonfunctional requirements of the communications specification.

So again we want to make sure that manufacturers have thought about ways to mitigate these types of failures such that it may not adversely affect the patient.

So the verification and validation considerations really depend on the level of risk associated with the device itself; the purpose of the interface on the device, the anticipated use of the device and the target system and the intended use of the device.

So testing should demonstrate that the interactions on the electronic interface perform as intended and comply with the intended specifications. And for devices meant to be used with a limited number of specific devices, appropriate testing to demonstrate safe operation with those specific devices would make sense. For devices meant to work with many devices it may be more appropriate to test the device against the interface specification and with a representative device for verification.

For devices meant to be part of a larger, interoperable system the manufacturer should conduct testing to reasonably ensure that the medical device will continue to safely and effectively fulfill its intended use when it is assembled, installed and maintained according to its instructions.

So appropriate testing may include testing to assure that the device continues to operate safely when data is received in a manner outside the bound of the parameters specified; establish and specify failsafe states for critical functions such as delivering energy or real-time monitoring; verifying only authorized users that are allowed to exchange information with the interoperable medical device; validating the user interface and determining if the users are capable of correctly using the interface; assuring that reasonably foreseeable interactions only cause correct operation of other network systems and nothing else; and testing that simulates real-world use of the device.

The labeling should contain the functional interface and performance requirements of the electronic interfaces that may be used to connect medical devices with other electronic equipment. Labeling may include materials within the packaging of the device, the instructions for use or device-specific information posted on the manufacturers Website.

There may be different directions for different users and further recommendations can be found and later on in the guidance document that I will go over for the pre-market submission. So we'll talk more in-depth about labeling.

And then also manufacturers should really consider the use of consensus standards when they are available. We really encourage the use of consensus standards to support medical device interoperability. The standards that support interoperability are often for manufacturers and also other stakeholders such as health care delivery organizations, system integrators, system designers, installation technology professionals who work in healthcare settings.

So these – there can be many types of standards that can help support interoperability. And as I said previously we did do an initial recognition of many standards that support interoperability and cyber security. We have continued to review different standards that support interoperability and have recognized others as well.

If ever there is a standard that you would like us to consider recognizing we ask that you go to the link below and suggest the recognition of that standard. And you can always go to our database to see if the standard that you're interested in using is recognized by the FDA.

Within – I'm just going to (ahead) – within our standards that we have recognized they really are many times design standards. And while recognition – what we have recognition to encourage the use of standards, it is very possible that it makes more sense for a manufacturer to use another design for how they maybe define elements of their interface. And we just ask that it is clearly explained to us and we'll get into that more in the pre-market submission part of the prog.

So contents of the pre-market submissions, so we're not talking about – we're not going to talk about what which particular devices or how you would decide whether or not you need a pre-market submission. But for those devices that do need a pre-market submission for medical devices intended to exchange and use information with or from other products, technologies or systems FDA recommends sponsors provide basic information similar to what would be normally provided to support other functions or features on the medical device.

So really what we're saying here is that normally if you would have an electronic interface that had a particular function we would recommend these

same criteria would be looked at. So what we're doing here in this guidance is we're really trying to clarify that for devices who are meant to use these interfaces and to allow the device to be an interoperable medical device.

So I also want to note that there may be FDA guidances or special controls applicable to the device. Also some device-specific standards may contain interface specification recommendations as well.

So in the first part in that your normally submitted device description that you would have in your pre-market submission a sponsor should discuss each externally facing electronic interface. If the interface is only meant to be used by the manufacturer this should be clearly stated. And if the interface is meant to be used with only specific devices, then those devices should be clearly specified as well.

And we also ask you to note that the level (of) detail provided in the device description may depend upon the intended interoperable scenarios in which the manufacturer expects the interoperable medical device to be used. So clearly if it's only meant to be used by a manufacturer not – you probably don't need to include as much information describing the interface as to which – as compared to an interface that is meant to let's say connect to an infusion or some other medical device.

The description of the electronic interface may include some or all of the following elements based upon the claims of data exchange and use made for the medical device. The purpose of the interface and the role that the device plays within an interoperable system if the interface is meant to transmit, receive or exchange information but standards were used, requirements for timeliness and integrity of the information such as a sample rate or transmission rate; communication format rate and transmission method.

Are there any limitations or things that the user shouldn't do? Are there any contra indications for cautions and warnings? What are the functional performance requirements? And the application programming interface if the device is software that can be used by other software or medical device or system.

Now for the risk analysis manufacturers should consider the risks that are associated with interoperability. The reasonably foreseeable misuse and the reasonably foreseeable combination of events that could result in a hazardous situation. The risk control measures may not be necessary for risks that are broadly acceptable. And there may be additional hazardous situations that arise when more than one medical device is connected within a system.

And the manufacturer should specify which mitigations are implemented and which ones are necessary for safe use and may require implementation by other parties such as the party responsible for setting up or installing.

We recommend including an analysis of the interface or interfaces on the device, the intended connections and any effects that the connections may have on the device performance. The submitted analysis should include normal elements in a risk analysis and address the risk control measures for reducing unacceptable risk to acceptable levels, (stop) tolerant behavior, boundary conditions and failsafe behavior.

Any risks potentially arising from security vulnerabilities that may be involved with the presence of an electronic interface. And risks arising from normal use as well as reasonably foreseeable misuse.

For the verification and validation of the electronic interfaces a sponsor should include results of verification and validation testing for the electronic interfaces; the nature and extent of the validation depends upon the risks associated with the device; the purpose of the interface, the anticipated use of the device and the interoperable system and the intended use of the device.

For devices only meant to be used with a limited number of specific devices documentation demonstrating appropriate testing with those specific devices may be appropriate. For devices meant to connect with a class of devices or to be used in any device or computer system documentation demonstrating appropriate testing with a representative of the class of devices or within the context of the system may be more appropriate.

Documentation which demonstrates the following performance testing should be included in the submission; verification that the device interface meets its design specification; validation that the device interface performs as intended; determination and verification of the information that should be provided to a user to connect to the interface and to allow the user to ensure that the connection has been made correctly. And verification that the device will perform safely and within specifications when used under normal conditions and as normal conditions that are reasonably likely to occur.

So the degree of documentation for verification and validation can vary based upon the risks. If the purpose of the interface along with the intended scenarios for use of the interface do not add significant risks to the operation of the medical device then test summaries may be sufficient. For example if you have an infusion pump that is intended to receive patient data from several devices such as a pulse oximeter, ventilator, blood pressure monitor and that it's going to use this data to change infusion pump settings, complete test reports most likely should be provided to the FDA in the plan submission.

If a non-invasive blood pressure monitor has an interface intended to allow historical data to be downloaded to a computer then a summary of the testing performed on the interface may be sufficient. Information regarding the electronic interface on the device should be included in the labels so that the device can be used safely and effectively for its intended use.

So we really want these labels to contain the appropriate amount of information so that somebody can connect and use the information as it was designed. So information as I said should enable users to connect to the device in a specified manner and should give proper instructions on how to use the connection of the device in the ways again in which it was designed.

This should include any limitations of the connections to discourage any misuse of the device. It also should contain any precautions, warnings, contra indications. Validations of labeling regarding the use of electronic interface should consider human factors as well.

So just going to walk through a couple scenarios and talk about what we would – what we are thinking about should be in the labeling for these different scenarios.

So in Scenario 1 the device is meant to interact with only a few specific devices. In this case the labeling should explicitly state that the medical device is meant to connect with those specific devices listed and include the version. And then it should not be used with other medical devices or non-medical device technology.

In the second scenario if the interface is only meant to be used by the manufacturer's technicians for software updates or diagnostics it should be



explicitly stated in the labeling that the use of electronic interface is reserved for representatives of the manufacturers.

In Scenario 3 the device is not meant to be interoperable. So the labeling should state that the electronic interface found on the device is not meant for connecting to other medical devices or non-medical device technology.

And then finally in Scenario 4 if the electronic interface is meant to interact with other medical devices the guidance selects a series of items to consider placing in your labeling. So consider certain information is needed for someone to properly connect to your device through the electronic interface and use the information as described.

Consider what information is appropriate based on the risk associated with the device, the purpose of the interface, the anticipated use of the device and the interoperable system and the intended use of the device. Consider the use of standards for the electronic interface. The FDA recommends the following information be included in the device labeling as appropriate based upon the purpose of the medical device interface.

And I would like to emphasize when we talk about device labeling this doesn't have to be labeling on the box. This can be instructions for use. It can be information found on the internet. And so it's important for manufacturers to figure out the most appropriate way to convey the information to the users.

So we recommend that the following be included; the purpose of the interface including any devices, device types, interface standards specification of software with which it is meant to connect; who are the anticipated users of the interface; whether the connection is meant to control the operation of another device.

Specifications for each of the interfaces – this could be the specifications could include – could be a logical way forms prototype, accuracy, frequency of response as well as the necessary performance and functional requirements from a device related to the sending or receiving of data.

A list of the data attributes being exchanged, the summary of the testing performed on the interfaces to verify interoperability claims and any activity suggested for a user to verify safe operations. And the case where testing was performed an interface specification and verified with representative device the manufacturer should specify the representative's device used.

Any relevant standards used and certifications received; any methods used for time synchronization; a description of any fault tolerance behavior; boundary condition testing or failsafe for critical functions that will allow the user to understand how to use the interface correctly; any known limitations, contra indications, precautions and warnings; any recommended connections; recommended settings or configurations for the electronic interface. And instructions for specific users such as IT personnel on how to connect or install and disconnect or uninstall the device.

So I wanted to also direct your attention as we've gone through the information in the guidance document that we do have a Website on medical device interoperability. It is underneath – it's within the digital health part of our Webpage. And it contains a lot of information and resources that you can go to as well as of course links to the guidance document.

And if you have any questions regarding interoperability or any digital health related questions we do have a digital health email address at the bottom of

this slide. And I will say that the group itself is very good at getting back to people on their questions and it can be a great resource.

So at this time we'd like to open it up to questions.

Operator: Thank you. To ask a question please press Star followed by the number 1. Please unmute your phone and clearly state your name and company to present your question. If your question has been answered, please press Star, 2 to withdraw your request.

One moment please for the first question.

(Heather): So one of the things while we're waiting for the first question that I was – when we went over the comments on the draft guidance document one of the things that we found is that we tried to provide clearer language throughout the guidance document. We found that sometimes there, you know, the wording that we had used maybe was misinterpreted.

One of the things that often is – that people have questions on as well was the purpose of the interface. And we were very careful to avoid the use of the intended use of the interface because we wanted to avoid having it confused with the intended use of the medical device as defined when you are submitting an application for medical device.

And so while the purpose of the interface may be included in the intended use because one of the main functions of a medical device most likely and electronic interface on a device would not be part of the intended use.

We'll take our first question.

((Crosstalk))

Operator: First question from (Aflan Schmitt) from GetGo Research. Your line is open.

(Aflan Schmitt): Hi. Thank you for having this presentation. When I think of electronic interfaces I think like most people I think of wired interface. But not too long ago we had a lot of data moving around by SneakerNet by USB6 and the like.

Would you also be thinking of that as an electronic interface? Or should we think of just the wired connections.

(Heather); No we are thinking of the other connections as well. Any place where it's an interface where you could exchange and use information. I mean we certainly know that there are many different technologies out there. So not just the wired connections.

(Aflan Schmitt): Good. Thank you for that clarification.

(Heather): We'll take our next question.

Operator: (Robert Evell) from Cenify your line is open.

(Robert Evell): Hi, thank you for the presentation. I had a question – you had an early slide about time synchronicity. So are you talking about like between a Smart Phone like the clock on our Smart Phone like if there's an app on that that's controlling a medical device. And then if there is a clock on the medical device itself?

(Heather): Yes. So anything that may be connected. I mean we've heard and heard in the past where people have done studies and looked around an OR and looked at

the time on different devices and found that they can be quite dramatically different.

And if you had software let's say that's recording events from different medical devices in a situation like that or an EHR that's collecting information from different devices and if you have the reporting of times that are very different you can understand how that information would be difficult to interpret after a surgery or whatever it might be.

(Robert Evell): Right. Thank you for (unintelligible).

Operator: Next question from (Amir Shaw) from Teva. Your line is open.

(Amir Shaw): When specifying (unintelligible) and to.

(Heather): I'm sorry the person asking the question dropped off.

Operator: (Amir), your line is open sir. We have you cutting out. Can you present your question again please?

(Amir Shaw): (Unintelligible) have to have (unintelligible).

Operator: Once again we do apologize we're not able to get the question at this time. We'll move on to the next question. Or once again we are showing no questions. But as a reminder please press Start, "1" to ask your question. One moment please.

We do have questions coming through, one moment please.

Next question is from (Jacob Brown) at Springborn. Your line is open.

Woman 1: Hi. I have a question about the – first of all thank you again for the presentations today. It's been extremely helpful. I have a question about the submission, the 510(k) submission. Would you expect to see a special section describing how interoperability has been managed or would you anticipate that it be the various elements be incorporated into the rest of the submission content?

(Heather): I don't think that it would need to be its own section. It could certainly be incorporated. We currently know that a lot – what goes into interoperability. There is related software as some of the information may be very much obviously related to cyber security. So I would incorporate it most likely in where you're talking about your software section and your cyber security; wherever would make the most sense.

Woman 1: Thank you.

Operator: And the next question from Tom Johnson from Medtronic. Your line is open.

Tom Johnson: Yes my question is I see a lot of (unintelligible) the (unintelligible) and the 21st Century hears that. Could you help me understand – I just see a lot of (unintelligible). And then...

(Heather): No, yes. Yes we can certainly understand that. Certainly if you have a very just simple transferring of data out of your device as you know within the 21st Century Cures Act that would not be considered part of the medical device. And we would not be reviewing that necessarily in terms of the detail that's seen within the guidance document.

But so we certainly understand that. There are of course more complex connections among devices that are sort of beyond that sort of what we, you know, we're calling MDDS or what's talked about in the 21st Century Cures Act, where you could be taking information and analyzing it and then interpreting it. And then actually changing the settings on the device based upon that information.

And so when it you get especially into those more complicated connections that's where the information here would, you know, definitely be applied.

Tom Johnson: Thank you.

John Murray: This is John Murray. I'd like to add to what (Heather) was saying that we will not be regulating medical device data source systems. We don't get to the (league) devices. But when you connect your device to any other type of connection whether it's a power connection or communication connection, whatever, we do have some concern or some issue related to the impact.

And the expectation here is that if you intend to hook it up to something that you've at least thought of what the risk considerations are. So that's important to us. If you hook it up to an established specification there's probably minimal risk there. But if you have a special connection it's the same kind of impact analysis or thinking that goes along with using power out of a wall or (battery) or things like that.

So we will be thinking about the impact of connectivity even though we won't directly regulate or review medical device data systems.

(Heather): And I – this is (Heather) again. I would like to add too – that's also why the front of the guidance document was sort of written the way it was. So we

recognize there are many things out there that we don't regulate to a pre-market submission whether or not we regulate them all when we're talking about some of the things covered in the 21st Century Cures Act.

So we really wanted to put down our thinking out there for people in terms of what are sort of, you know, good considerations for you to be thinking about when (connecting) with medical devices or having connecting a medical device with other systems.

Operator: The next question is from (Sonya Phillips). Your line is open.

(Sonya Phillips): Hi. Our defibrillators continue to interoperative device.

(Heather): I'm sorry did you ask if defibrillators were considered a priority device, is that what I heard?

(Sonya Phillips): No, interoperative device. Our defibrillator on the discussed specification that we're talking about?

Linda Ricci: So this is Linda Ricci. Any device that has an external communicating aspect to it could be considered to have aspects of interoperability. But we're really relying on you as the manufacturer to define what that interoperability means for your specific device. I mean if you're looking at an automated external defibrillator that has some ability to communicate off of the device for a specific reason, then there'll be aspects of this guidance that would apply to that.

(Sonya Phillips): Okay, thank you.

Operator: Next question from Larry Liu of Verb Surgical. Your line is open.



Woman 2: Hi this question is on behalf of Verb Surgical. So we were wondering around interoperability of medical devices. When you (assess) the risks associated with interoperability we are aware of the risks in our device or maybe the connection of our device to another. But how do we assess the risks associated with the other device that we have no idea some of the risks that are associated with that other device that we are connecting to.

Is there any FDA guidance on how to address that? Thank you.

(Heather): Yes so we certainly understand that that's a concern. What we hope is that you can define the specifications are – what are the requirements of your interface when somebody else is connecting with them. And that you have taken the sort of appropriate precautions to mitigate risks for devices that you foresee connecting with them.

And hopefully through defining the types of devices and that through those requirements would sort of have some control over that. But we certainly understand that if somebody else is connecting to your device that there are some things that really should be controlled on their side or considered on their side in terms of the risk associated.

Yes so and that's why we used the language that we had that you really should be considering the risks with normal use and any foreseeable misuse with the device as well. But obviously unforeseen uses – those are things that we would not be expecting you to control because we certainly understand that.

John Murray: Yes, this is John Murray. There was a lot of questions about this in the draft document, the question of scope of risk management. And I think (Heather) is correct, (Heather) is right on mark here. You don't own the risk management

of the entire universe. But you do need to identify those risks that you know about or have had experience with.

And there's also a part of the presentation I saw that you may provide instructions for use to control some risk that you may anticipate outside of your control but that you want the user to take care of. So you have different risk methods here that you can employ to solve that problem.

Woman 2: Thank you so much.

Operator: Next question is from (Corinne) from (Boticel). Your line is open.

Man 1: Hello. My question here is like, you know, we are the manufacturer for the (fritz) used only for (flip) and we believe that, you know, our software work well the third party medical device. So my question here is how – what (unintelligible) like, you know, we are only the third application and (the) test software which is known that we are getting (new) at.

But we believe that our software, the (unintelligible) software is (completely below) interoperable work with a third party medical device.

(Heather): Sorry I caught a lot of what you're saying, but not all of it. Were you asking about – so you're talking about it – your device is software only? And that...

Man 1: It's (current) device so it's just applications or it's the software.

(Heather): Yes.

Man 1: And this (unintelligible) you asked whether the (unintelligible) risk. But our software worked interoperable with a third party medical device.

(Heather): Okay. So it works – it's interoperable with a third party medical device. And what was the question about that?

Man 1: So what factor as a manufacturer of the (search) software we need to consider. What factor we need to consider to (see) interoperable?

(Heather): What do you need to consider. So I – obviously it sounds like you've been working with a particular device but you would need to consider what are the risk of operating with that particular third party device. What type of verification and validation test show that you do interact well with that device. Also are there any security issues or other things, risks to mitigate, that you've taken into account.

So I do think...

Man 1: Okay.

(Heather): ...yes, the things that we've gone over in this guidance would apply to that.

Man 1: Okay, okay.

Operator: We are showing no further questions. We'll turn it back to our host, Irene Aihie.

Irene Aihie: Thank you. This is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH (unintelligible) Webpage at [www.fda.gov/training/cdrhlearn](http://www.fda.gov/training/cdrhlearn) by Friday, November 3. If you have

additional questions about today's presentation please use the contact information provided at the end of the slide presentation.

As always we appreciate your feedback. (At the conclusion) of today's Webinar please complete a short, (unintelligible) and question survey about your FDA CDRH Webinar experience. The survey can be found at [www.fda.gov/cdrhwebinar](http://www.fda.gov/cdrhwebinar) immediately following the conclusion of today's live Webinar.

Again thank you for participating. And this concludes today's Webinar.

Operator: Thank you for attending the conference. This does conclude the call. You may disconnect at this time.

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