Which aspects of CTTI's findings deserve immediate attention?

Early involvement is key!

What worked and what did not

Understanding what endpoints regulators accept

Developing a framework for sponsors for clinical validation

Validation requirements

engaging with patients/caregivers

Streamlining the validation of endpoints

Example of value are needed

FDA acceptance for novel endpoints

Which aspects of CTTI's findings deserve immediate attention?

How use of DHTs will be evaluated during regulatory inspections

Streamlining of validation

Developing a framework for manufacturers on what the needs of industry are

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developing a mechanism for early and frequent interaction

Validation requirements

Encouraging collaboration

Appropriate level of evidence

Streamline the validation of endpoints

Which aspects of CTTI's findings deserve immediate attention?

define health concepts that are meaningful

What are potential solutions to the CTTI findings that require immediate attention?

It is too complex - need multiple inputs

open source algorithms

Provide blueprints of use cased, including validation details

A framework that highlights examples where digital endpoints fit within traditional clinical endpoints.

FDA needs to initiate the process of a formal guidance

A means to collaborate across companies

Provide a list of FDA-accepted novel endpoints

managing the resistance to change mindset

Providing a framework of guidance for manufacturers to help sponsors

What are potential solutions to the CTTI findings that require immediate attention?

A mechanism by which to engage early and frequently with FDA outside or in addition to the current standard meeting opportunities

As we try to advance the use of novel digital endpoints what would you say is the #1 lesson learned, so far?

Patients need to come first. The endpoint must be patient relevant.

Its a long process

Lack of clarity of what is "enough" to validate a new endpoint

data integration from various systems remains an increasing challenge especially as the pace of technology continues to accelerate

If you could identify one thing in the near term – say, 6 months – that is needed to advance the use of the these endpoints, what would it be?

Describe how we'll ideally be using these novel endpoints 2 years from now and what are the 1-3 things that are critical to getting us there?

Collaboration with health authorities

Multiple endpoints will be used as primary endpoints

We need to coordinate the collaborations

using in regulatory submissions. 1. validate that the novel endpoint is meaningful, 2. assure quality of collection, assessing, analyzing and controlling date

Small pilot studies validating the endpoint, which can help gain acceptability from regulators and sponsors