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How to handle connectivity issues in electronic Clinical Outcome Assessment (COA) clinical studies?

kayentis · Thursday, September 22nd, 2016

Connectivity is key when using electronic Clinical Outcome Assessment (eCOA) tools in clinical studies. But what are the requirements of eCOA tools regarding the internet, what are the connection options, and what can be done if there is no internet connection? These eventualities can occur more frequently than might be expected.

Why being connected is so important for an eCOA solution?

- **For quick information exchange**

First at all, a good internet connection is needed to share information quickly with all stakeholders. Data entered at a study site or at a patient's home need to be available to study staff for processing as quickly as possible. Similarly, information reported centrally, eg by doctors and study monitors, should be readily available on the device.

- **And secure storage of data**

While data is safely managed on the device, secure remote data storage is only achieved once uploaded to a central location. Devices are breakable, and can be stolen or lost. It is therefore vital to have data uploaded in a timely and regular manner.

Which type of connection is prefered when implementing an eCOA device in a clinical study?

1. Wi-Fi, the first choice

Wi-Fi is the best option. It is widely used, user-friendly and efficient. It is available on almost all device models. At a patient's home, it is probably the preferred option.

But Wi-Fi can also be prohibited, reserved for site use only, or can suffer from a weak signal. When authorized, the use of a Mi-Fi accessory allows Wi-Fi to be setup easily and without causing problems to the site.

2. Mobile network, the second choice

The use of mobile network is the next best option. It is also popular and is available on all

smartphones on a large number of tablets. The main benefit is that it is self-contained. The provision of an eCOA device with a mobile connection chip removes any reliance on the study site. Although network coverage can be problematic: in some geographical areas or in some parts of a particular building a mobile connection may not be available or could be poor or unstable.

3. Wired connection, the backup option

A wired connection should be considered as a backup option in the absence of a Wi-Fi or mobile network connection. The dependence on a wired connection, physical connection to the local network could be problematic for a mobile device.

What if an internet connection is not available?

For the above reasons and more, internet connectivity could be more complicated than expected. As such, the following options should be integrated into the design of the eCOA application:

- Allowing some operations not to require a network connection, eg. entering patient data.
- Performing asynchronous synchronization, eg. allowing data to be sent automatically as soon as a network is detected (this would require pending transmissions to be indicated).
- Providing eCOA devices with multiple connectivity such as both Wi-Fi and a mobile network with the capacity to switch automatically to the best connection.
- Monitoring the device remotely to detect and react on poor or failing connectivity.

Connectivity is essential to the success of the implementation of an eCOA solution in a clinical study. As such it is crucial to offer several connectivity options within the device and to anticipate the sporadic use of devices while not connected.

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This entry was posted on Thursday, September 22nd, 2016 at 9:58 am and is filed under Optimizing clinical trials
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