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The Signal

EMA Draft Guidance: Here's What It Tells Us About BYOD

The European Medicines Agency (EMA) draft guidance released this past June on "computerized systems and electronic data in clinical trials" to replace their 2010 reflection paper on eSource. The agency details the use of eCOA and other eClinical solutions in clinical studies.

They underline a preference for electronic collection of COA data, at least in most circumstances, by stating: *"There is no requirement or expectation that the sponsors and investigators use computerised systems to collect data; however, the use of electronic data collection (EDC) tools if implemented and controlled to the described standard, offers a wide variety of functions to improve data completeness, consistency and unambiguity, e.g. automatic edit checks, validation checks, assisting information and workflow control."*

Perhaps most interesting is the section discussing the bring-your-own-device (BYOD) approach to eCOA: *"Both ePRO data and clinician reported outcome data may be captured by privately owned devices such as mobile phones, tablets, computers and wearables, i.e. BYOD."* This may indicate the agency's expectation to see an increased use of BYOD solutions to provide app- or web-access to electronic patient-reported outcome measures (PROMs).

Much like the U.S. Food and Drug Administration (FDA), the EMA underlines the importance of providing provisioned devices to patients unwilling or unable to use their own devices, so they can still participate in the trial.

The EMA focuses mainly on aspects of data security and privacy in relation to BYOD use: They discuss the importance of ensuring app-level authentication is in place (as it cannot be assumed that users have implemented password protection), limiting local on-device storage of data, and defining operating systems and devices that are supported with up-to-date data security.

There's plenty of published evidence on measurement equivalence of PROMs on different media, so it's not surprising that the EMA chose to focus on less developed topics. They do, however, make a point that *"qualification activities should take into account different screen sizes,"* providing the example that visual analogue scales should follow the same *"general presentation"* independent of device. Unfortunately, "general presentation" is not clearly defined, but this likely refers to general format and layout properties as opposed to

maintaining the same precise length of the scale across different devices. For example, there is now enough evidence to support measurement equivalence with different lengths of VASs across different devices.

A recent BYOD equivalence study compared VAS implementation across 156 BYOD users with devices of different shapes and sizes and found very strong measurement equivalence. This is in addition to many more published studies comparing different implementations to a 10 cm line.

Need further guidance on BYOD for eCOA? Contact our team today.

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