Operating System Upgrades Do Not Adversely Affect eCOA Completion Behavior
When Using a Bring Your Own Device (BYOD) App.

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Abstract

OBJECTIVES
To understand the effect of operating system upgrades managed by subjects when using their own device (Bring-your-own-device – BYOD) to collect eCOA data on ongoing eCOA data completion rates, based on device usage data collected in a large ongoing clinical trial.

METHODS
eCOA completion compliance and device-log data were explored to understand the impact of operating system upgrades on eCOA app use and diary completion for subjects participating in a large ongoing clinical trial (n=10,000+, ages 50 to 85+, 20+ countries). The clinical trial collected eCOA data using a BYOD app solution, with provisioned handsets for subjects unable/unwilling to use BYOD.

RESULTS
eCOA compliance was 83% (BYOD: 85%, Provisioned: 82%). BYOD was used by 2,500+ patients in the study; 48% used iOS and 52% used Android apps. During the active phase of the study, 49% of subjects completed one or more operating system upgrades. Some subjects using iOS devices completed up to 14 minor/major operating system upgrades during the study. The eCOA compliance rate amongst subjects completing operating system upgrades was 86% compared to 83% for BYOD subjects not completing operating system upgrades on their handsets.

CONCLUSIONS
The current study appears to show that operating system upgrades have no effect on eCOA completion compliance when using BYOD. While the lack of control over operating system upgrades has been suggested to be a potential barrier to BYOD use and eCOA app compatibility, the performance data form this study suggests that this aspect is unlikely to limit the application of BYOD in future clinical trials.
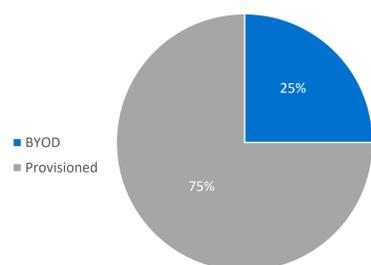
Figure 1. Device provisioning rates

Introduction

The patient's voice is critical to ensure the development and provision of patient-centric healthcare. Sponsor-driven clinical research is striving to position patients at the center of developing new medicines. eCOA represents a robust solution for delivering patient-centred clinical research.

Traditional approaches to collecting eCOA in the field have involved the deployment of provisioned handheld devices to patients inside clinical research trials. These provisioned devices are provided by the sponsor and are used by the patient for the duration of the research trial. More recently, however, there has been a move to enable patients to use their own devices ("Bring Your Own Device" - BYOD) to run study apps (e.g., for ePRO), as opposed to being provided with a second device for the purposes of the study. This approach may have advantages for a patient such as convenience and familiarity of their own device, reducing the burden of carrying and maintaining a second device and may even improve ePRO compliance rates since patients are more likely to keep their own device with them at all times.

Unfortunately there is a perception that BYOD alternatives are more vulnerable to technical challenges since the device does

Introduction cont.

not have the same level of sponsor control as a provisioned device. One area of concern for BYOD is the unpredictable nature with which device manufacturers push updates to their operating system (OS). It is perceived that these types of upgrades could pose a threat to the stability of eCOA apps which could threaten data input and in turn affect compliance and missing data. This poster explores whether OS updates affect compliance in eCOA research.

Methods

This daily diary study has currently recruited over 10,000 patients, aged 50 to 85+ years. Patients access the ePRO system via an app using their own mobile device or one provided to them by the study site if they do not have a suitable device, or are unwilling to use their own. The study is being conducted in over 20 countries worldwide.

Results

Device provisioning rate
Device provisioning rates are shown in Figure 1. Handsets were provided to 75% of patients. The remaining 25% used their own mobile devices to access the eCOA system.

BYOD device characteristics
BYOD was used by 2500+ patients to access the eCOA platform. Of these, 52% used Android mobile devices and 48% iOS (Apple) devices (Figure 2).
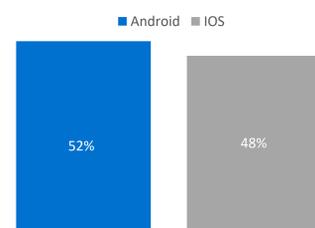

Figure 2. BYOD Device characteristics

BYOD Operating System upgrades
Of the subjects accessing the eCOA platform via BYOD 49% completed one or more operating system (OS) upgrade(s). The distribution of updates is outlined in Figure 3. One subject completed 15 minor/major operating system upgrades during the study.[1]
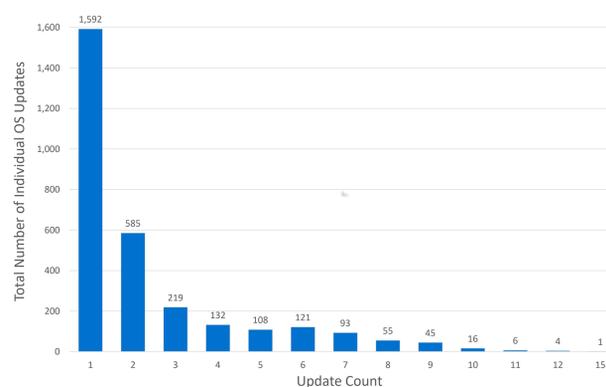

Figure 3. Total Number of Individual OS Updates by Update Count

The majority of OS upgrades occurred on IOS (Apple) devices (Figure 4). 77% of BYOD users using IOS equipped devices had one or more OS update whereas 23% had none. In direct contrast the opposite was found for BYOD users equipped with the Android OS. Only 23% of Android equipped devices had one or more OS update while 77% had no updates.
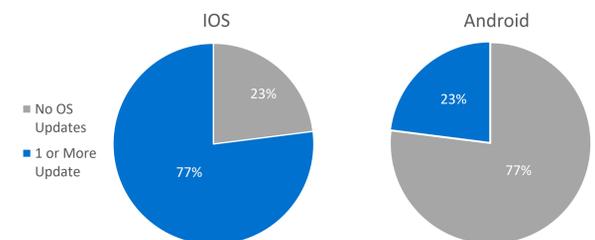
Results cont.

Figure 4. Percentage of Updates Based on OS

eCOA Compliance
Overall eCOA compliance for the entire study cohort (BYOD & provisioned devices inclusive) was 83%.

The compliance rates segmented based on device provisioning, BYOD device characteristics and BYOD OS updates are displayed in Figure 5. Compliance rates across the segments displayed no statistically meaningful differences.

Compliance rates based on device provisioning showed 82% for provisioned devices and 85% for BYOD devices.

Compliance rates based on BYOD devices characteristics showed that for patients using Android compliance was 83% and for patients using IOS devices compliance was 87%.

Compliance rates based on BYOD operating system upgrades showed that for patients who had no OS updates compliance was 83% while for those patients who has one or more system update compliance was 85%.
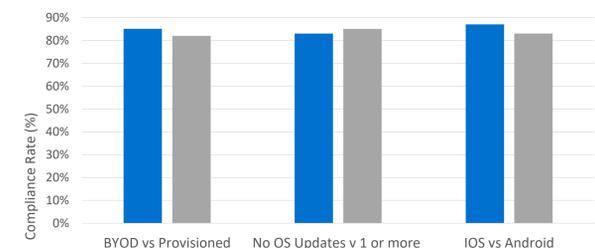

Figure 5. Compliance Rates across Groups

Discussion and conclusions

Despite enthusiasm for allowing patients to use their own devices to collect eCOA inside clinical trials this study indicates that provisioning rates of BYOD remain well below sponsor provisioned devices. Of patients who did access the eCOA solution via BYOD there was a fairly equal split between Android and IOS users and this may seem somewhat surprising given that global OS market share weighs heavily in favour of Android. Nevertheless it appears that 'native' Android users may have been more likely to accept a provisioned device which could explain the convergence of the figures observed.

OS upgrades appear to have virtually no meaningful effect on compliance data. Between patients who had no system upgrade and those who had one or more upgrade there was only a small insignificant difference in compliance. A similar convergence finding was observed when comparing OS. There was only a small insignificant difference in compliance despite the number of operating system upgrades being heavily skewed toward IOS devices. This finding, in a large sample of patients, is supportive of the use of BYOD.

References

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