Study Participant Device Utilization When Offered a Choice Between BYOD Versus Sponsor-Provided

PCR256

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Introduction

Collection of electronic patient-reported outcome (ePRO) data has become a routine feature of clinical studies. The use of specifically designed study applications loaded onto handheld devices allows for the convenient collection of such data away from study sites. These devices may either be handhelds provided to participants by study sponsors via their sites (sponsor-provided; SP) or participants' own smartphones (Bring-Your-Own-Device; BYOD).

Choosing between SP and BYOD is a decision that can be driven by various parameters, both for study sponsors (and their CROs) as well as for study participants:

- Uniformization of data collection
- Cost of provisioning
- Familiarity/comfort with app installation
- Inclusivity (socioeconomic factors)
- Helpdesk preferences
- Study design features (e.g., use of daily diaries, event-driven assessments, complex data collection schedules, infrequent device use, image capture needs)

The aim of the study was to understand participant preference between SP and BYOD when given the choice and how study and participant characteristics influence that choice.

Methods

Post-hoc analysis using historical, aggregated data from a Clario in-house database was conducted. Parameters investigated were:

- Development phase
- Therapeutic area (TA)/indication
- Age range of participants

The studies included were (i) run and completed between 2018 and (early) 2024, (ii) had offered the participants the choice between BYOD and SP, and (iii) had transmitted – for any given study – at least one data point from a BYOD device plus one from a SP to the study's ePRO database housed by Clario.

- Study country information was an integral part of the actual database.

Descriptive statistics were derived by the authors and BYOD-vs-SP device utilization patterns were used as a proxy for device preference.

Results

Characteristics of the selected sample:

- Twenty-six completed studies fulfilled the selection criteria. Table 1 and Table 2 show the distribution of studies across different developmental phases and high-level TA, respectively.

- Total number of participants in the retained sample: 10,128 participants

Among the 10,128 individual participants BYOD was slightly more often used as the device of choice over SP (58% and 42% of users, respectively).

While the studies covered all phases of clinical development (Table 1), no patterns of device utilization emerged by phase.

A broad variety of TAs were represented in the sample (Table 2), with Vaccines/Infection and Neurology (incl. Pain) at highest frequency. Of note, established design patterns in different medical indications could skew device usage designs and it may therefore be difficult to draw conclusions from direct comparisons of device preferences in different TAs

Phase	N of studies	% (of 26)	Percent BYOD
I	2.5*	9.6	73%
II	10	38.5	67%
III	7	26.9	50%
IV	2	7.7	74%
Other/Unknown	4.5*	17.3	51%

*To maintain a total of 26 studies, two studies spanning two phases were divided and counted as half a study in each phase

TABLE 1: Distribution of Studies across Development Phases

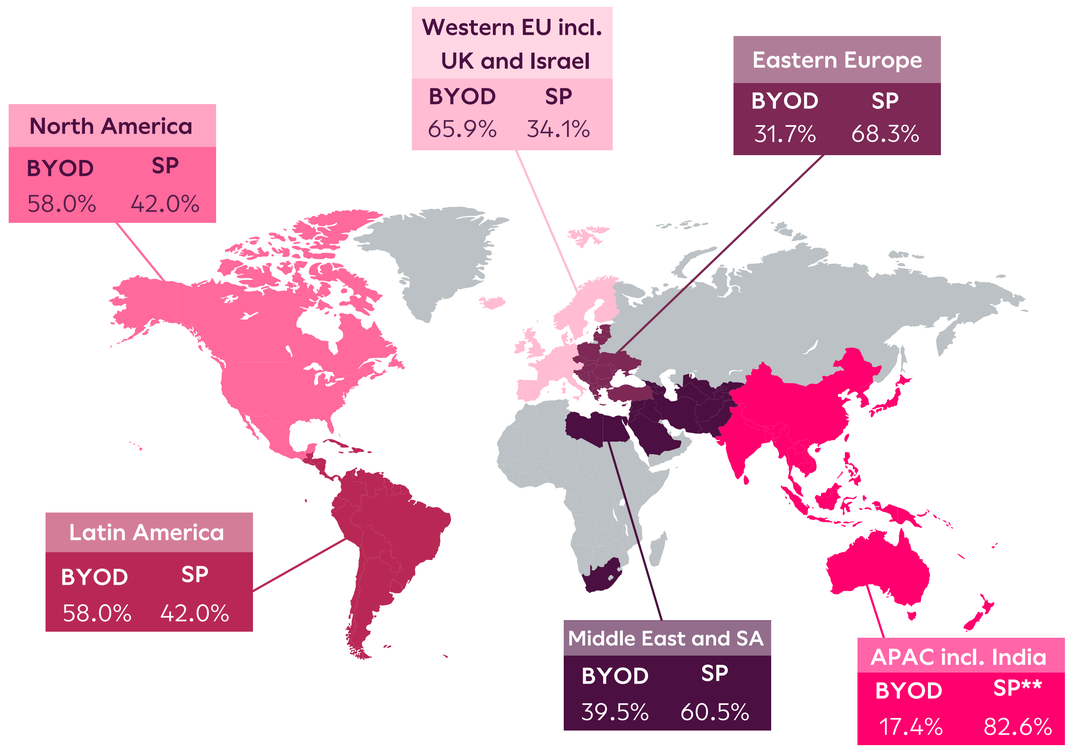
TA	N of studies	% (of 26)	N of participants	% BYOD
Vaccines & Infection	8	30.8	2880	78.8
Neurology & Pain	8	30.8	1908	43.9
Dermatology	3	11.5	1176	61.0
Gastrointestinal	2	7.7	697	85.4
Respiratory	2	7.7	538	84.4
Oncology	1	3.8	664	4.1
Cardiovascular	1	3.8	1477	35.7
Endocrinology	1	3.8	788	62.1

TABLE 2: Distribution of Studies by High-Level Therapeutic Areas

Fifty-four countries were represented in the sample and covered all major regions of the globe (Figure 1), with BYOD utilization ranging from 17% in APAC to 66% in Western Europe (including UK and Israel).

- The countries most frequently included across the identified studies were the USA (N=22 studies), Spain (N=12), Italy (N=11), Germany (N=10), and the UK (N=9).
- Countries with the highest utilization rate for BYOD (≥80%) vs. SP included Austria, Switzerland, Sweden, Türkiye, Belgium and Finland.
- Conversely, the countries with the lowest utilization of BYOD (<10%) were Portugal, Slovakia, Greece, China and Japan. Of note, China is characterized by a constitutive preference for SP.

There was no obvious relation between device utilization and age when those studies were compared that had recruited participants from distinct (non-overlapping) age groups.



** APAC: Near-constitutive use of SP in China might skew results

FIGURE 1: Device Utilization Rates Across Geographic Regions

Conclusions

- When given the choice, BYOD seems to be the marginally preferred device (vs. SP) globally, across various developmental phases and TA, taking account of the limitations listed below.
- Our preliminary analysis indicates a relative absence of relations between study and participant characteristics and BYOD-vs-SP device preference. In contrast, an analysis by geographies suggests that countries and regions used for ePRO studies may contribute in a relevant way to the preference for BYOD vs. SP.
- Further analyses should focus on the possible combined effect of multiple drivers on device utilization patterns.

Limitations

In addition to the necessary high-level nature of the present analysis, key limitations of our post-hoc approach include:

- The data available for this study did not include self-reported preferences, but instead used metadata about actual utilization as a proxy for preferences.
- Unknown device provisioning decisions (and their strategic drivers) made by sponsors for their studies, which might have resulted in different availabilities of the BYOD and SP alternatives across our study sample.
- A lack of visibility on site personnel's role (or site bias) regarding device choice during decision time, which might overlay participants' personal motivations.

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