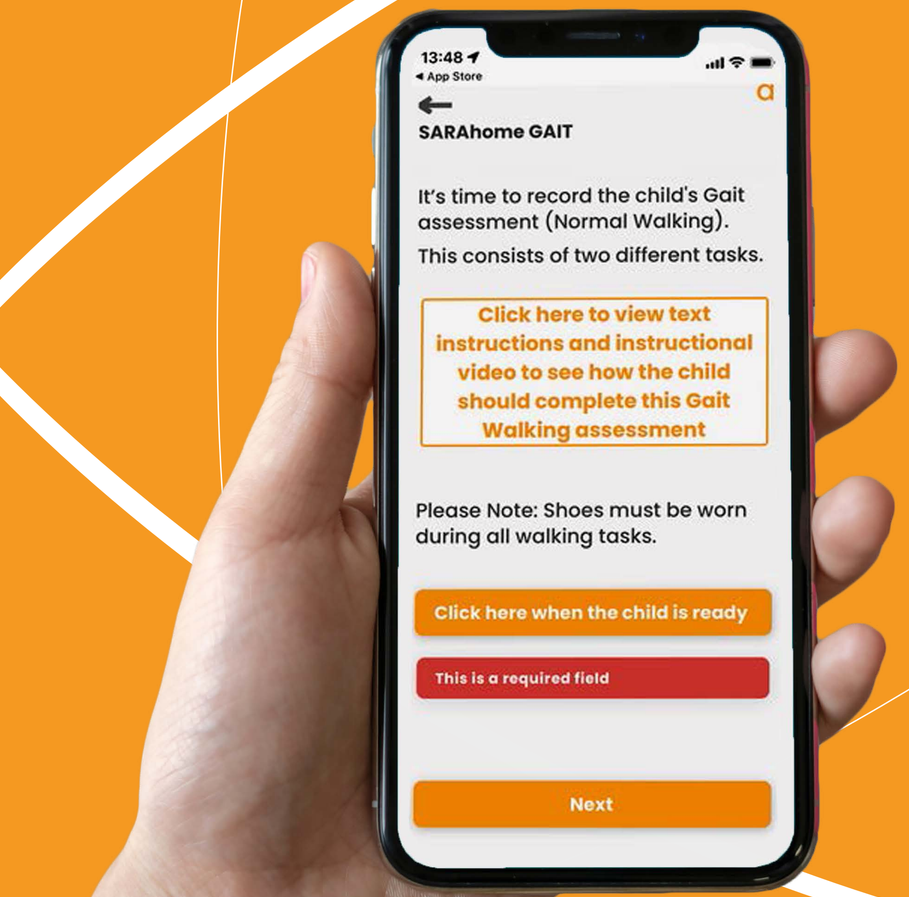
Provisioned Devices vs Bring Your Own Device (BYOD) in Clinical Trials

aparito



Background

The last decade has seen a paradigm shift towards hybrid trials and DCTs. This transformation reached its peak during the COVID-19 pandemic with unprecedented challenges faced by the clinical community, including interrupted trials and potential impact on the lives of millions of patients.

Adoption to decentralised (DCTs) and hybrid studies accelerated over the COVID-19 pandemic. With reduced disruption to participants' daily lives as well as reducing costs and simplifying logistics this is a welcome change.

Despite concerns around privacy and data security the use of smartphones in real-world data (RWD) collection has increased exponentially, received support from regulatory agencies and keeps evolving, making it efficient and accessible.

"Pragmatic and hybrid clinical trials, including decentralized trials that are conducted at the point of care – and that incorporate real world evidence (RWE) - can help clinical trials become more agile and efficient by reducing administrative burdens on sponsors and those conducting trials, and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data that's being collected."

Breaking Down Barriers Between Clinical Trials and Clinical Care:
Incorporating Real World Evidence into Regulatory Decision Making (FDA, 2019)

Regulatory Guidance

Both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) support the use of electronic tools to collect patient data. Recent regulatory developments to support this evolution include:

Guideline on computerised systems and electronic data in clinical trials (March 2023, EMA).

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints For Regulatory Decision-Making Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders (Draft Guidance, FDA, April 2023).

Use of smartphones in DCTs and hybrid clinical trials reduce costs, simplify trial design and data collection, and increase participant recruitment and retention (Ali et al. 2020). These benefits, along with recent regulatory guidance ensure continuing adoption of smartphones.

Smartphones, ePRO and eCOA

The adoption of smartphones to gather ePROs garnered attention in 2015. The "mPower" explored the technical feasibility of using iPhones's ResearchKit to collect data and observe changes among patients (> 9000) with Parkinson's Disease (Bot, B et al, 2016). By enrolling a large number of patients, the volume of data generated may help understand progressive neurodegenerative conditions like PD. In another study (Perry B et al, 2019) 76% of the participants expressed their willingness to participate in a clinical trial using smartphones and tablets.

Furthermore, there are encouraging signs in the use of BYOD in hospital settings which could translate to innovative use of BYOD in hybrid clinical trials. In a hospital based study (Chien SC et al, 2023), patients used their own smartphones or tablets to control and manage routine tasks (for eg turning lights on, adjusting their beds, TV). Results suggested that nurses were satisfied with the approach.

Provisioned Devices (PD) vs Bring Your Own Device (BYOD) in clinical trials

The choice between a PD or BYOD in clinical trials is based on the protocol data capture needs, sponsor preference, patient needs, and risk mitigation. Ethics committee approvals can also influence the decision. However, when it comes to the quality of data - a core requirement in a clinical trial - evidence is growing for there being no difference.

In a key observational study (Hudgens Set al, 2022), exploring the equivalence of data, patients with Chronic Obstructive Pulmonary Disease (COPD) completed their weekly Patient Reported Outcomes (PROs) either on a PD or BYOD for 15 days, then switched device types for 15 days. PROs collected longitudinally via PDs vs BYOD were compared. Completion of PROs was high and scores were equivalent between PD and BYOD, supporting use of BYOD in addition to PD for collecting PRO data in COPD studies and in demographically diverse patient populations.

Researchers from the University of Cambridge, Royal Papworth Hospital and Pulmonary Hypertension Association UK initiated a collaborative survey to better understand patients' needs and help to design a future trial, StratosPHere.

The survey collected data from over 100 patients with pulmonary hypertension as part of a project by Aparito's Patient Group Accelerator.

The survey found (Table 1, overleaf) that in the >65y group:

93% own their smartphones

93% are willing to share their data

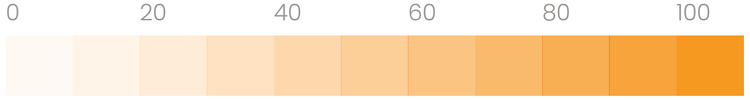
93% are agreeable to telemedicine

83% are confident with apps

The results highlight that most participants have their own smartphone, and use it with confidence. The results also debunk the myth of older adults not being comfortable with technology and with sharing their data.

Table 1
Acceptance of technology by older patient groups in PAH

		Male (n=26)	Female (n=86)	Age <35 (n=14)	Age 35-64 (n=78)	Age >65 (n=20)	White British (n=102)	Other ethnicity (n=10)
PROMs	emPHasis-10 covers ways PH affects life	82.0	89.3	88.0	86.0	92.0	87.4	91.1
	Quality of sleep since PH	41.6	45.7	48.3	44.3	50.6	44.9	46.7
Digital Tech	Smart phone ownership	81.3	98.4	100.0	94.6	93.3	94.4	100.0
	Wearable activity tracker ownership	18.8	40.3	42.9	39.3	20.0	37.5	16.7
	Confidence with apps	81.7	89.8	96.4	88.6	82.7	88.9	79.2
	Willingness to share digital data	98.3	98.4	100.0	98.2	93.3	97.2	100.0
Decentralised	Agreeable to telemedicine	92.3	93.2	100.0	92.3	92.9	92.5	100.0
	Perception of hospital tests reflecting feelings	77.1	84.9	83.3	83.9	81.8	84.7	58.3
6MWT	Perception of 6MWT reflecting function	45.5	73.8	83.3	73.0	40.0	66.7	80.0
	Feel able to do digital 6MWT	92.3	78.0	83.3	82.7	71.4	82.1	60.0
	Appropriate environment for digital 6MWT	100.0	84.7	83.3	84.6	100.0	88.1	80.0
Research participation	Previous PH clinical trial participation	15.4	24.6	33.3	26.4	7.1	25.0	0.0
	Agreeable to further linked research	75.0	79.2	75.0	79.8	75.0	80.1	56.3



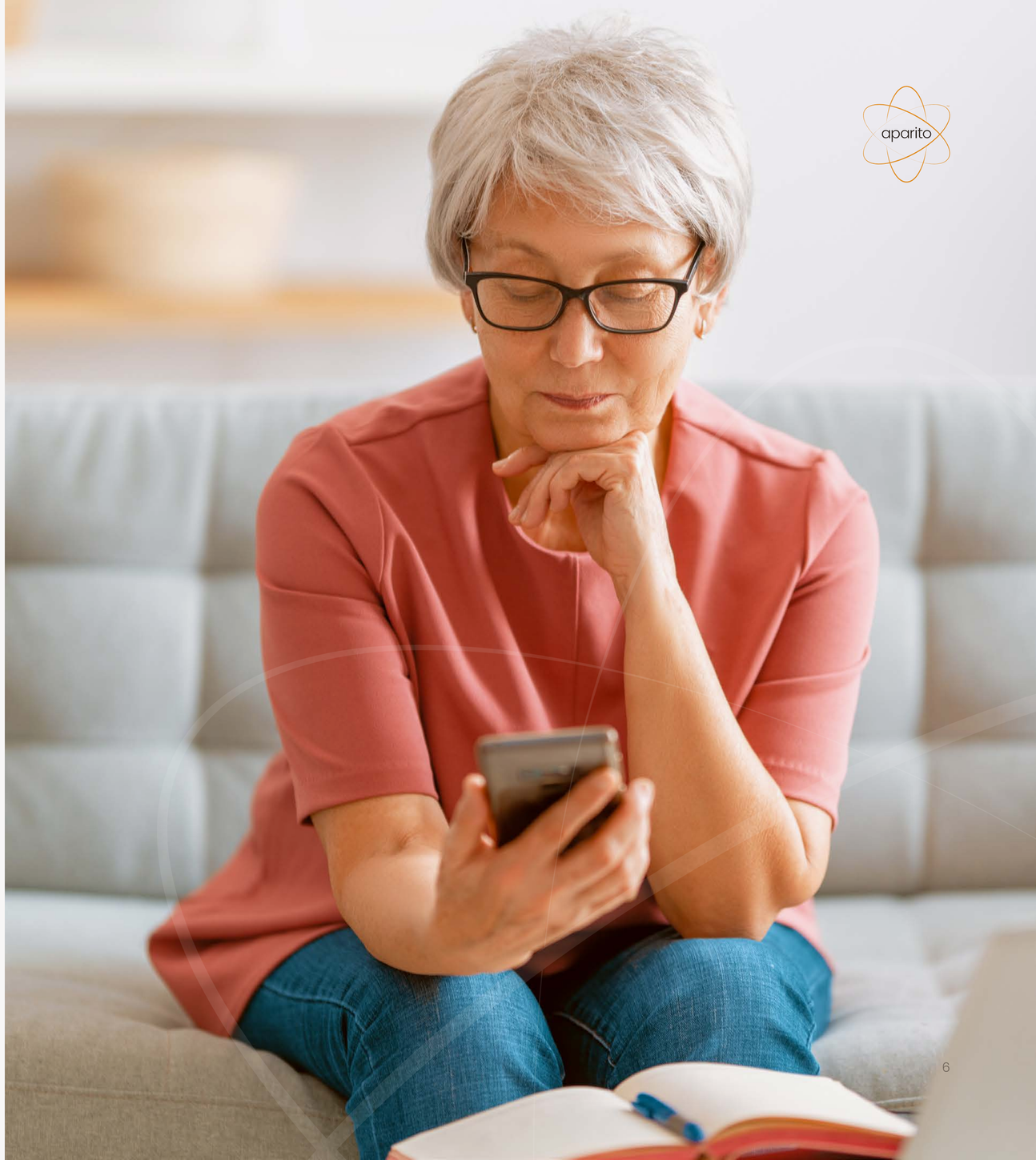
J.Newman & M.Toshner, 2023

Provisioned Devices (PD) vs BYOD: Our Experience

Over the past nine years Aparito has been at the forefront of this shift to using devices to gather ePROs and eCOAs. We have supported DCTs and hybrid clinical trials run by pharma, biotech, CROs, patient groups and academic researchers, using both PD and BYOD.

We believe that the rapid adoption of smartphones lends itself to a BYOD strategy.

We present a summary of three ongoing global clinical trials where our platform Atom5™ has been used to support our view.



Study #1

This is a phase II randomised, double-blind, placebo-controlled clinical trial to evaluate the safety, efficacy and pharmacokinetics of an Investigational Medicinal Product (IMP) in the treatment of an orphan brain malformation.

The study had 17 clinical sites based in the USA. 50 subjects have been recruited to date. A total of 34 PDs (two per site) were distributed. Only two participants needed a PD of whom one patient subsequently withdrew from the study.

Study #2

This is a randomised Phase II/III study consisting of a Phase II single-blind, dose-evaluation phase and a Phase III double-blind, placebo-controlled phase to assess the efficacy and safety of a monoclonal antibody for treatment of a rare bone disease.

This study has 38 clinical sites spread worldwide including North America, South America, UK and Australia. 31 subjects have been enrolled so far. 32 PDs were shipped to the sites, two devices have been lost or misplaced and only two participants needed a PD.

Study #3

This is a prospective, observational, multicentre, mixed methods study to gather the natural history and experience of patients living with a rare musculoskeletal inherited disorder.

The study has 14 sites across the UK and Europe. Devices were provided as requested by sites. Two provisioned devices were sent to be used on an “as-needed” basis to one site, based on ethics requirements, only one has been used to date.

Table 2
Overview of our PD vs BYOD experience

	Study #1	Study #2	Study #3
Study Phase	Phase 2 randomised double-blind study	Phase 2 and 3 randomised, placebo-controlled double-blind study	Observational, prospective, multicentre, mixed methods study
Operating System	Android	Android	Android
Total n=patients recruited	72	31	24
Total provisioned devices used vs issued	2 out of 30	2 out of 34	1 out of 2
Percentage of patients requiring provioned devices	2.7%	6.4%	4.1%
Number of sites	17	38+	14
Countries	USA	North America, South America, UK, Austrailia, Canada, Europe	UK, Europe

Benefits and risks

The challenges that the sponsor must assess while deciding whether to use PDs or BYOD are diverse. We share what we have learnt, along with our clients, about the benefits and risks of using PD or BYOD for sponsors, sites, and patients.

Table 3
BYOD or PD: Benefits and risks

	Benefits	Risks
BYOD	Reduced costs (shipping, lost devices, inventory management).	Heterogeneity of devices may impact app functionality, impacting data collection.
	Reduced site burden (inventory management and training patients on both device and study app).	Screen size may impact response scales
	Reduced patient burden (there is no need to carry an additional device or learn how to operate/ charge a new device).	Device memory might affect optimal use
	Reduced carbon footprint.	Participants might disable notifications from the study app and compliance of the study app.
PD	Study specific devices with the option to manage the end-to-end participant experience.	Management of personal identifiable information accidentally stored on PD.
	Option to ensure notifications are not disabled.	Increase in patient burden (need to carry and maintain a second device).
	Doesn't exclude participants without personal smartphones.	Delays in delivery of PDs leading to delay in recruitment.
		Increased site burden (manage inventory).
		Increased costs

Benefits and risks continued

While the BYOD approach enables swifter and easier roll out of decentralised and hybrid clinical trials the option to use provisioned devices on an ‘as needed’ basis helps ensure that the study does not exclude any participant who is unable to participate due to lack of a personal smartphone. We recommend using PDs as an exception rather than the rule, to be applied on a case-by-case basis.

Aparito can support sponsors using a PD or a BYOD strategy for their study. We provide adequate training to the clinical staff at Site Initiation Visit (SIV) and well before the enrolment of the First Patient First Visit (FPFV). During the first clinical recruitment visit, we can support site staff so that patients can receive appropriate guidance to use the dedicated study app confidently during the study.

Atom 5™

Atom5™ is a software solution for digitising clinical trials and developing novel digital endpoints to accelerate drug development. It consists of a smartphone app (available on iOS and Android) for trial participants and a clinician/site portal for clinical/site staff.

As an integrated solution for clinical trials, Atom5™, supports video eCOAs, ePROs, telemedicine, and eConsent via one smartphone app.

Designed and built by regulators and clinicians it is 21 CFR Part 11, GDPR and HIPPA compliant by design. Our eConsent is provided in partnership with DocuSign.

It is available in 193 countries and 125 languages, Atom5™ supports hybrid and decentralised clinical trials with assessments at scale and accelerates clinical trials for sponsors and study teams.

We understand rare diseases.

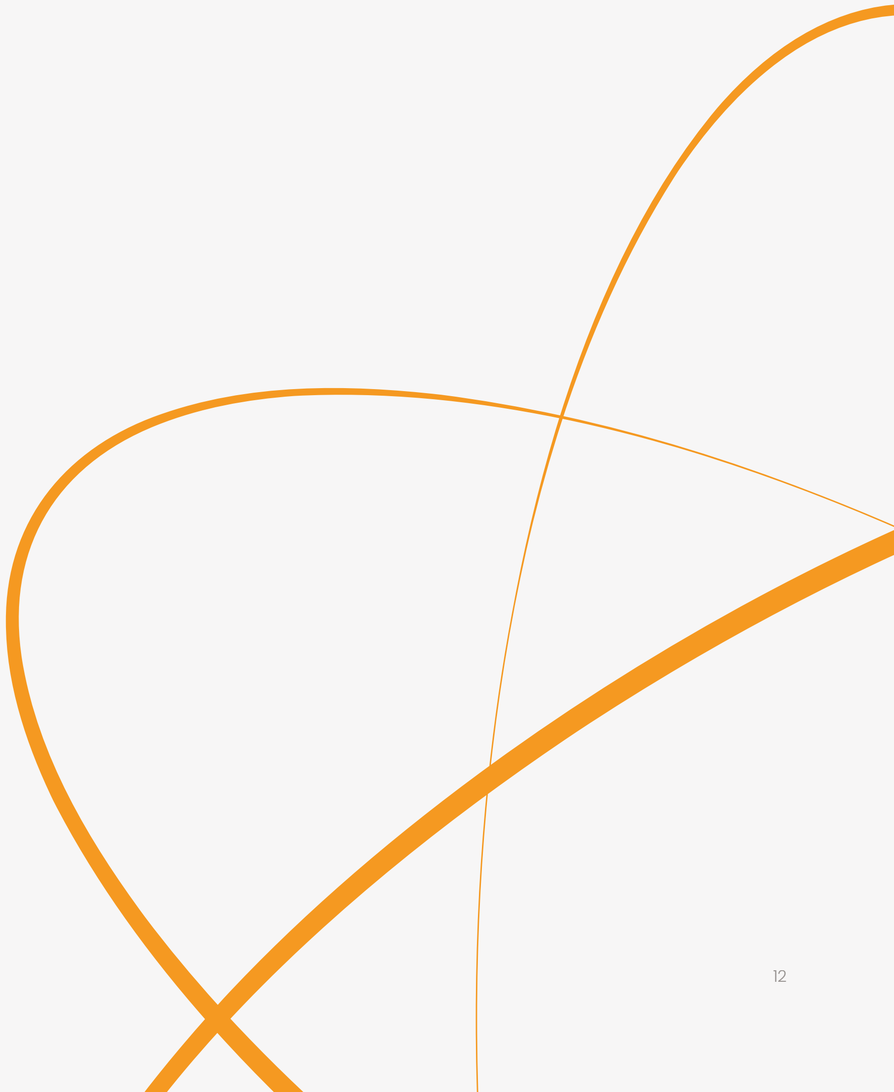
With >10,000 rare disease patients across 30 different rare diseases, enrolled across 20 countries in clinical trials from phases I through IV, we have an in-depth understanding of the regulatory, clinical and patient needs. Additionally, through our own internal R & D, we have developed and validated endpoints, co-created with patients for use in rare disease studies.

Summary

Adoption to decentralised (DCTs) and hybrid studies accelerated over the COVID-19 pandemic. Both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) support the use of electronic tools to collect patient data and have guidelines to enable the use of smartphones to collect ePROs and eCOAs in clinical research. Patient engagement improves with BYOD strategy and offers a wealth of opportunities for innovative eCOA and ePRO collection that can benefit patients and their clinicians.

Our experience over the past nine years has shown that the rapid adoption of smartphones supports the use of a BYOD strategy in DCTs and hybrid clinical trials. We recommend using provisioned devices as an exception rather than the rule, to be applied on a case-by-case basis.

With newer and better ways to collect high quality data, including ePROs and eCOA, the future of using smartphones and linked devices through the entire drug development life cycle is set to grow exponentially.



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