



Single Day Event

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ePRO & eCOA with wearables

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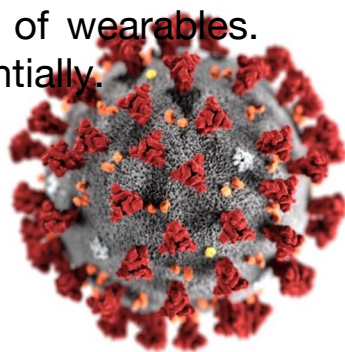


Background

The world was moving just fine till Q1 2020. All studies were running as expected and all patients were coming to site (wherever required) as expected.

Then suddenly Covid struck and the world went into lockdown. The pharma world was awestruck as many of the studies which could not have been stopped (like Oncology trials) had to stop. Years of work and billions of dollars was about to go in vain when they realise that there is already a solution available for quite some time, lying unused, mostly because of the inertia.

The option was to use eConsent, ePRO & eCOA with the added help of wearables. Around a billion wearables are in use today and the market is growing exponentially. These wearables are advance enough to be used for help in ePRO and eCOA.





Terms & Acronyms

eCOA (electronic Clinical Outcome Assessment): An electronic assessment that may be influenced by human choices, judgement or motivation and may support either direct or indirect evidence of treatment benefit.

ePRO (electronic Patient Reported Outcome): Data reported electronically directly verbatim by subjects, self-report or interview.

eConsent (electronic Informed Consent): Electronic informed consent is using electronic systems and processes that may employ multiple electronic media including text, graphics, audio, video, podcasts and interactive web sites, and card readers, etc., to communicate information related to the study and to obtain and document informed consent.

Wearables: Electronic devices that can be worn as accessories, embedded in clothing, implanted in the user's body, or even tattooed on the skin. The devices are hands-free gadgets with practical uses, powered by microprocessors and enhanced with the ability to send and receive data via the Internet.



Parking Lot Syndrome

“Parking Lot Syndrome” – Generic term occasionally used in clinical research industry to describe patient’s action of filling diaries and questionnaires right before a clinic visit/ while waiting in the parking lot before doctor’s appointment.

If Parking Lot Syndrome has to be avoided, site staff should give patients reminder call, followed by a confirmation call. Is it feasible ? For all studies for all patients

Wearable can help with this problem of reminding, confirming and they can take some the vitals reading too.



Benefits & Motivations





Benefits

- ☐ What about Quality ?
- ☐ How much is the gain in the Productivity ?
- ☐ What is the Enablement for Physicians, Sponsors and Patients ?



Benefits

- ❑ **Controlled Experience:** As the system/application are uniform across the sites, the individual experience can be controlled.
- ❑ **Follow ups:** System/applications installed on Smartphone/Wearables can prompts user automatically and nudge them to fill the questionnaire at the appropriate time.
- ❑ **Increased Compliance (Regulatory & Patients):**
 - ❑ Secure Login/Password
 - ❑ Date time stamped in the audit trail
 - ❑ All other informations recorded in the audit trail



Benefits

Cost:

Paper: there is direct and indirect cost of (Sometime, It can be as high as \$20 per page)

- ☐ Printing,
- ☐ Mailing,
- ☐ Data Entry
- ☐ Data cleaning



eCOA/ePRO:

- ☐ One time cost for the system, application, smartphone & wearables
- ☐ Cost saving in less data entry, less data cleaning, printing & mailing
- ☐ Fewer site support needed incurring fewer payments





Motivations

- ❑ Uniquity of high speed internet:
 - ❑ 63% - World
 - ❑ 90% - Developed Countries
 - ❑ 57% - Developing Countries
 - ❑ 27% - Less developed Countries
- ❑ Majority of the world population has smart phone
- ❑ ~1B wearables in the market. Quite good in recording multiple vital parameters (including ECG, Blood Oxygen & Heart Rate)
- ❑ Apple Researchkit
- ❑ Google Health
- ❑ E Consent
- ❑ Maturity in the eCOA/ePRO designs

Reference : [Global internet access rate 2005-2021](#)

Barriers & Reality

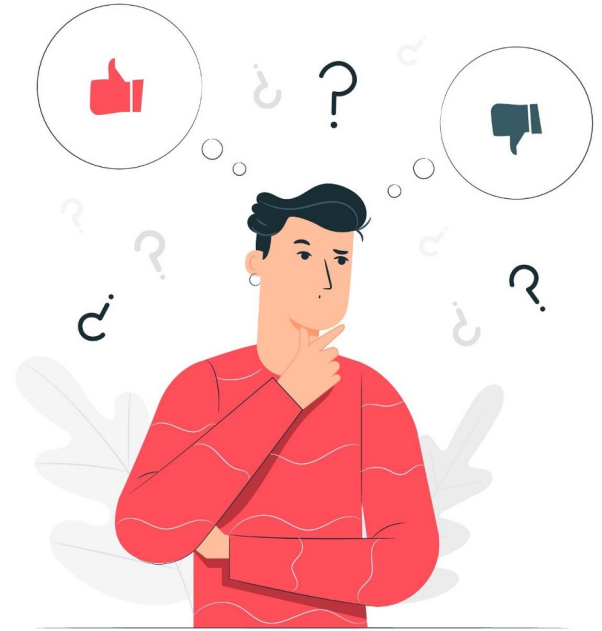




Barriers & Reality

- ☐ Expensive (perceived)
- ☐ Devices/Logistical
- ☐ System/App Usability
- ☐ Fit with study population
- ☐ Integration with CDM/EDC systems
- ☐ Translating the current paper PRO to electronic form
- ☐ Regulatory

Considerations





Technology

- ❑ Access to Smartphone and other devices like wearables
- ❑ Connectivity to high speed internet
 - ❑ Hot spots to be provided as backup
- ❑ Device provisioned or BYOD
 - ❑ 80% had smartphone, rest to be provided
- ❑ Ability to collect data offline, where data reside with the device locally for the time being and then can transferred to the EDC when connected
- ❑ Data Privacy
- ❑ Data Accuracy



Regulations

eCOA/ePRO should follow the ALCOA principles:

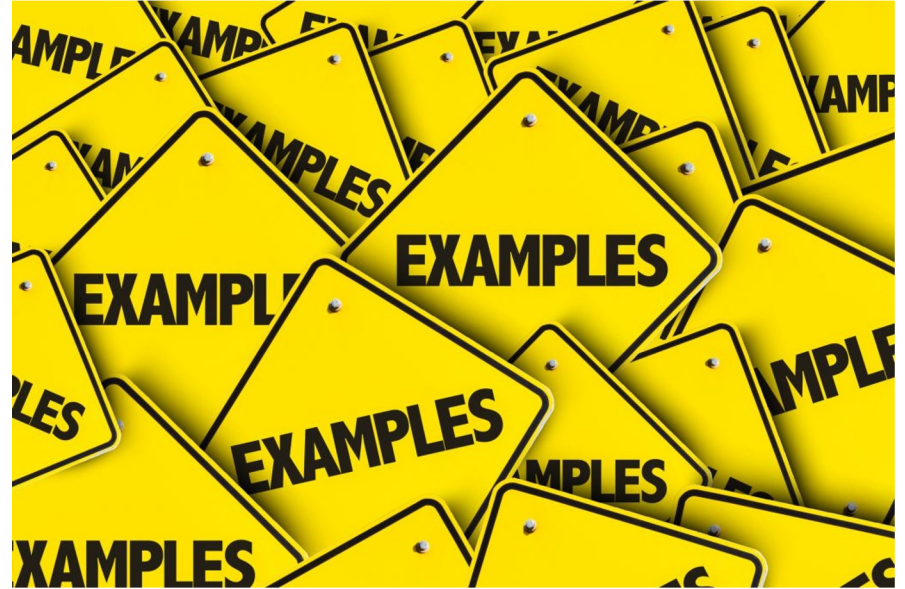
- ☐ Attributable -> Login access/control
- ☐ Legible -> Digital, structured
- ☐ Contemporaneous -> Better track or control
- ☐ Original -> Direct data from the system
- ☐ Accurate -> Edit checks, data checks can be implemented to have accurate data



Contents

- ❑ **Design:** Questionnaire design should be start with the study protocol. Designed should ask themselves what is really needed and how to achieve that in simplest form.
- ❑ **Structure:** If the application & questions are structured properly, they are simple and the process is simple enough, we will have the data of very good quality.
- ❑ **Simplicity:** Participant may not care about the technology. The content should be simple enough to answer.
- ❑ **Languages:** Application/Questions/Process should be validated in many languages. There should not be any scope for misinterpretation.
- ❑ **Support:** Being to able to support participants through the process. Site or global support team should be trained enough to answer the support question or guide the participants though.

Use Cases & Examples





Use Cases & Examples

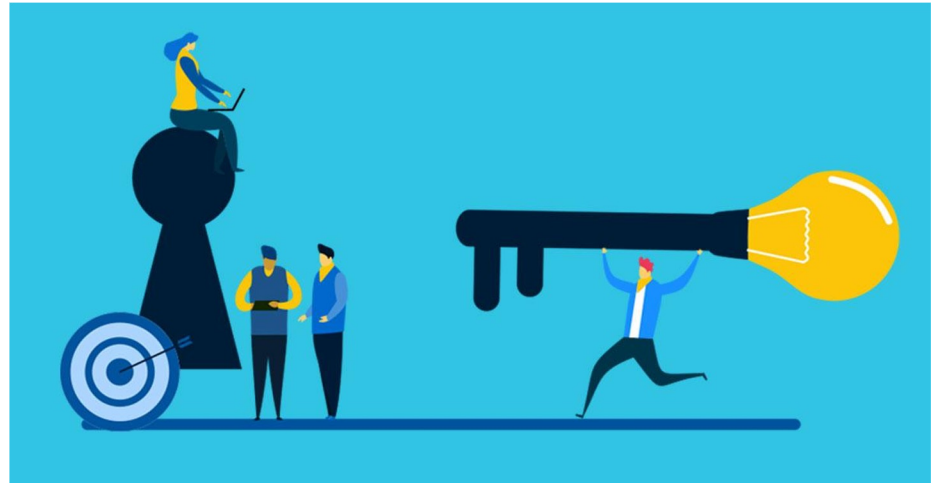
~1400 studies involving therapeutic areas including Asthma, Cancer, Schizophrenia and Diabetes have been conducted using wearable devices.

GlaxoSmithKline used Apple ResearchKit in a study for rheumatoid arthritis called PARADE, which was supported by an iPhone app.

The MSK Cancer Center teamed up with Medidata to assess myeloma patient's quality of life. These study patients will use wearables to continuously track their activity and sleep, and mobile apps to answer surveys about life quality aspects such as appetite and fatigue.

Reference: <https://www.mesm.com/resources/realising-the-potential-of-wearable-technology-for-clinical-trials/#:~:text=Wearables%20allow%20data%20to%20be,detailed%20manner%20during%20clinical%20trials>.

Key Takeaway





Key Takeaway:

The time has come for eCOA/ePRO to be added as a major part of any study. Below are the the points if taken care, will make sure the success for Sponsors and Patients alike:

- ☐ Training
- ☐ Audit Trail
- ☐ Data Quality
- ☐ Language Nuances
- ☐ Support

eCOA/ePRO increases accuracy, remove wrong interpretation, reduce time wastage for sponsor/patients. Overall it can help with the faster study closeouts.



Thank You

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Kumaresh Jha has 15 years of experience in life sciences & pharma domain as a Statistical Programmer. He has significant experience in multiple projects for Business Process as a Service (BPaaS). Kumaresh is proficient in statistical programming activities for Phase I to III clinical trials including CDISC Submission Packages, ADAMs and TFLs. He is part of the standards team to set up global standards for CDISC and TFLs. Kumaresh is currently Senior Product Manager for Saama's smart series auto mapper.



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